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Implant-supported single-tooth restorations: a 5-year prospective study

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Abstract

Background: Comparatively few studies are available reporting at least 5 years of follow-up data of implant-supported single-tooth replacements.

Objective: To evaluate prospectively the 5-year outcome of implant-supported single-tooth prosthetic restorations.

Material and Methods: Forty subjects (mean age 41 years), 23 males and 17 females, who required single-tooth prosthetic replacement for a missing tooth were recruited. A total of 45 self-tapping implants (Astra Tech® ST-implants) – 40 in the maxilla and five in the mandible – were installed in a two-stage procedure. Abutment connection was performed 3–6 months after implant installation. Clinical and radiographic examinations were performed at the completion of the prosthetic treatment and once a year during a 5-year follow-up period. The analysis of peri-implant bone level alteration was performed on subject and implant levels and by the use of analysis of variance and binary logistic regression.

Results: Three patients were lost during the 5 years of follow-up. One implant was lost after 2.5 years in function and another four implants could not be accounted for at the 5-year follow-up examination. The overall failure rate at 5 years was 2.6% (subject level) and 2.3% (implant level). The mean loss of marginal bone at the implants during the first year in function was 0.06 mm (SD 0.67) on the subject level and 0.02 mm (0.65) on the implant level. During the subsequent 4 years the annual change in peri-implant bone level amounted to -0.02 mm (0.22) on both subject and implant levels. Thus, the mean total bone level change over the 5-year interval was -0.14 mm (1.04) on subject level and -0.11 mm (1.00) on the implant level of analysis ($p > 0.05$). The frequency of implants with a 5-year bone loss of $\geqslant 1$ mm was 13%. Approximately 50% of the implants demonstrated no bone loss.

Conclusion: The present clinical trial on single-tooth replacements with the Astra Tech® implant system demonstrated that the bone loss during the first year of function as well as annually thereafter was small.

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

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Replacement alternatives for the missing tooth include removable or fixed partial dentures as well as adhesive restorations. Jemt (1986) described the technique of using endosseous, root formed implants to replace missing single teeth in the anterior maxilla. The advantage of utilizing implants for single tooth replacement was related not only to aesthetic demands but also to the fact that adjacent teeth were not engaged in the prosthetic rehabilitation. This technique was subsequently applied not only to edentulous sites in the anterior segments but also to load carrying posterior parts of the dentition (e.g. Jemt et al. 1990, Ekfeldt et al. 1994, Laney et al. 1994, Aviv-Arber & Zarb 1996, Henry et al. 1996, Fartash & Arvidson 1997, Palmer et al. 1997, 2000, Andersson et al. 1998, Scheller et al. 1998, Schwartz-Arad et al. 1999, Bahat 2000, Naert et al. 2000, Polizzi et al. 2000, Mericske-Stern et al. 2001, Gibbard & Zarb 2002, Simon 2003, Fugazzotto et al. 2004).

Mayer et al. (2002) emphasized the fact that the single tooth implant is a free standing unit that during function may not rely on the neighboring dentition for lateral and tangential support and that this may increase the risk of excessive load and failure. Esposito

et al. (1998) presented the outcome of a meta-analysis of 13 studies including >750 single-tooth implants of the Brånemark System® (Nobel Biocare, Gothenburg, Sweden). In the studies surveyed, only 19 failures were reported. In a recent systematic review, Berglundh et al. (2002) described the incidence of biological and biomechanical complications associated with the use of implants for single-tooth replacement. Eight prospective studies with at least 5 years of follow-up were identified. From the data reported it was evident that the incidence of (i) implants that were lost before loading (0.8%) and during function (2.5%) as well as (ii) technical complications (0.5 incidence/patient) in this type of rehabilitation was small but appeared to be dependent on the implant system used.

The aim of the present 5-year prospective study was to evaluate the outcome of single-tooth replacements by the use of implants of the Astra Tech® Implant system (Astra Tech AB, Mölndal, Sweden).

Material and Methods

The subject sample was recruited among patients who during a 3-year period were referred to the Departments of Periodontology and Prosthetic Dentistry, Göteborg University, Sweden. All subjects who were in need of oral prosthetic rehabilitation that would include single implant placement were invited to take part in the study. The following conditions were reasons for excluding a subject from participating:
Local: insufficient bone volume at the recipient site, i.e. need for ridge augmentation or sinus lift procedures.
General: uncontrolled diabetes, haemophilia, 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 University. Written informed consent was obtained from 40 subjects, 23 males and 17 females, who met the inclusion criteria. The mean age of the patients at time of recruitment was 40.9 years (SD 13.0; range 20–71 years). Twelve of the patients were current smokers with a daily consumption of 2–15 cigarettes.

A careful dental/periodontal examination was performed including assessment of plaque, gingivitis, probing pocket depth and radiographic bone loss at all remaining teeth. This was followed by oral hygiene instruction and, if indicated, periodontal therapy.

Implant treatment

The surgical treatment was performed under local anaesthesia and according to the manufacturer's manual. Sulcus incisions were made at the teeth facing the edentulous area and these incisions were then connected by a crestal incision placed on the lingual/palatal part of the edentulous area. A full thickness flap was elevated in buccal direction to expose the bone. As a rule the insertion depth of the implants was even with the buccal bone ridge. At 14 implant sites (31%), there was a markedly reduced bucco–lingual hard tissue dimension. At these sites implant placement resulted in a buccal bone dehiscence varying in depth from 1 to 6 mm. No attempts were made to augment the bone in such dehiscence sites. After implant installation, the flap was replaced and secured with interrupted sutures placed in the lingual/palatal incision line. Each patient received 1 g of penicillin (Kåvepenin®; Astra Läkemedel AB, Södertälje, Sweden) twice daily for 7 days from the day of implant surgery. The sutures were removed after 7–10 days.

A total of 45 screw-shaped and self-tapping Astra ST-implants® (Astra Tech AB) – 40 in the maxilla and 5 in the mandible – were installed (Fig. 1). Thirty-five patients had one implant placed, while five subjects received two implants placed in different jaw quadrants. Twenty-one implants were placed in the maxillary incisor region, 17 in the premolar region and two in the molar region. In the mandible, three implants were positioned in the premolar and two in the molar region. All implants had a body diameter of 3.5 mm (4.5 mm conical diameter), while the length varied between 11 and 17 mm (Table 1).

Abutment connection was performed in a second stage surgical procedure 3 months (mandible) or 6 months (maxilla) after implant installation. Standard, ST-Abutments® (Astra Tech® Dental Implant System), varying in length from 0 mm (35 cases) to 1.5 mm (one case), were used. The length of the abutment was chosen with the intention of having the abutment shoulder at the buccal aspect located 1–2 mm below the mucosal margin. Immediately after abutment connection, an acrylic crown restoration was fabricated and inserted as a temporary prosthesis.

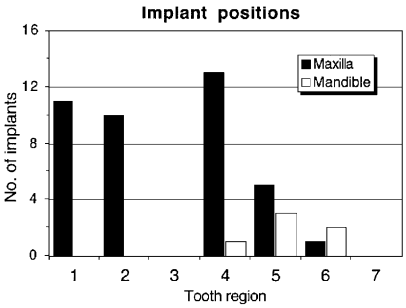

Fig. 1. Distribution of placed implants ($n = 45$) according to position in the jaws.

Table 1. Distribution of placed implants according to length and jaw

Implant length	Maxilla	Mandible	Total (%)
11 mm	6	3	9 (20%)
13 mm	12	1	13 (29%)
15 mm	18	–	18 (40%)
17 mm	4	1	5 (11%)
Total	40	5	45 (100%)

The prosthetic treatment followed the manual provided by the manufacturer. The final metal/porcelain prosthetic crown was completed and cemented with a normal setting, zinc phosphate cement (De Trey Zinc cement, De Trey Div, Dentsply Ltd, UK) about 4 weeks after abutment connection.

Careful oral hygiene instruction with emphasis on how to clean the implant region was given to all patients in conjunction with the installation of the prosthetic crown. In addition, the oral hygiene was checked at annual follow-up examinations and, if indicated, further instructions were given. Implant and tooth sites that at annual follow-up examinations showed bleeding following probing (BoP positive) were carefully debrided and polished by use of rubber cups and low abrasive polishing pastes.

Clinical examinations

At the baseline examination (i.e. delivery of the definitive prosthetic crown) and at annual re-examinations during the 5-year observation period, the following clinical parameters were recorded: pain from implant region, implant mobility, presence of plaque, mucositis (scored as BoP to a depth of about 2 mm below the

soft tissue margin) and probing depth (probing pressure 0.35 N) to the nearest millimeter. The assessments of plaque, mucositis and probing depth were performed at four sites of each implant (mesial, distal, buccal and lingual). In addition, the height of keratinized mucosa at the buccal aspect of the implant unit was measured.

Radiographic examinations

Postoperative radiographic examinations were performed at crown 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 individually fabricated film holders (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 working together interpreted the radiographs. For each implant, the radiograph was evaluated regarding (i) marginal bone height and change over time, as well as (ii) the bone-implant contact zone to detect loss of osseointegration. The marginal bone height was determined at the mesial and distal surface of each implant by measuring the distance between a reference point of the implant (Fig. 2) and the *marginal bone to implant contact* level with use of a magnifying lens ($\times$ 7). The error of the method used for assessing the radiographic marginal bone height was reported in a recent publication (Wennström et al. 2004). The mean difference between repeated readings was found to be 0.04 mm (SD 0.33).

Data analysis

The data analysis was performed according to the ''intent-to-treat'', i.e. all available data from all examination intervals were included in the analyses. For description of the data, mean values, standard deviations and cumulative frequencies were calculated. The primary outcome variables were implant loss and peri-implant bone level change. Clinical data were considered as descriptors. The peri-implant bone level data were analysed both on subject and implant levels.

Statistical analyses were performed with the subject as the statistical unit. Analysis of variance for repeated measures was used for statistical analysis of changes in peri-implant bone level over the 5 years of function. A binary logistic regression model, based on the case of a ''*bone loss of* >0.5 *mm*'' from baseline to the 5-year follow-up examination, was formulated in order to analyse possible interactions with some subject (*age*, *gender* and *smoking habits*) and implant (*anterior/posterior position*, *implant length* and *bone level at crown placement*) characteristics. In all analyses a *p*-value of <0.05 was considered to represent a statistically significant difference.

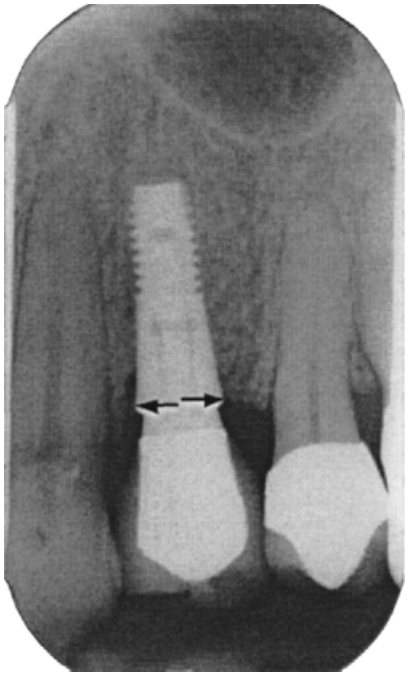

Fig. 2. Radiograph illustrating the reference point (arrows) on the implant used in the assessment of the bone-to-implant contact level.

Results

Table 2 presents the number of patients and implants at the time of implant installation, at crown insertion (baseline) and at the five annual follow-up examinations. One implant, replacing a maxillary premolar, was lost during function (removed after 2.5 years because of disintegration) in a patient who was a heavy bruxer, and four implants could not be accounted for at the 5-year follow-up examination. One patient died before crown placement (one implant) and two subjects (three implants) discontinued the scheduled annual re-examinations because of geographical relocation. At the time of the 5-year follow-up, one of the latter subjects confirmed in a telephone interview that the two single-implant restorations that he had received were still in place and that he had not experienced any subjective problems. The second subject could not be reached for an interview. Thus, the overall failure rate at 5 years was 2.6% on the subject level and 2.3% on the implant level. If the subject that could not be retrieved was considered as a failure case, the corresponding figures were 5.1% and 4.5% for subject and implant level, respectively.

Technical complications

Besides the failure with the loss of integration of one implant, a total of four incidences (in three patients) of technical complications occurred during the 5 years of observation. Two patients experienced a single incidence of loosening of the abutment retention screw; one during the first year after crown placement and one after 4.5 years. Following preparation through the crown, the abutment screw could be successfully re-tightened and the original crown maintained. An additional patient, who

Table 2. Number of patients and implants at the various examination intervals

	No. of patients	No. of implants	Reason for loss of implants to follow-up		
			Explanted	Drop-out	Deceased patient
Implant placement	40	45			
Abutment connection	40	45			
Crown placement	39	44			1
Follow-up					
1 year	38	43		1	
2 years	38	43			
3 years	36	40	1	2	
4 years	36	40			
5 years	36	40			

Table 3. Clinical conditions at 5 years (implant level; $n = 40$). Frequencies (%) and mean values (SD)

	Buccal	Lingual	Proximal
Plaque	3%	5%	13%
Mucositis (bleeding)	3%	8%	19%
Probing depth (mean)	3.0 mm (0.8)	3.2 mm (1.1)	3.8 mm (1.0)
PPD ⩽3 mm	80%	82%	61%
PPD 4–5 mm	20%	18%	30%
PPD ⩾6 mm	–	–	9%
Keratinized mucosa – mean width	2.9 mm (1.0)	–	–

Table 4. Mean bone level change (SD) from the time of crown placement (baseline)

	Subject level		Implant level	
	n	Bone level change	*n*	Bone level change
Baseline to				
1 year	38	− 0.06 (0.67)	43	− 0.02 (0.65)
2 years	38	− 0.14 (1.06)	43	− 0.08 (1.02)
3 years	36	− 0.07 (0.84)	40	− 0.03 (0.81)
4 years	36	− 0.14 (1.01)	40	− 0.09 (0.97)
5 years	36	− 0.14 (1.04)	40	− 0.11 (1.00)

had two incidences of loosening of the abutment retention screw, eventually lost the implant.

Clinical findings – 5 years

The patients maintained a high standard of oral hygiene throughout the study period. At the 5-year examination interval only about 8% of all implant surfaces were found to harbour plaque and 12% of the peri-implant sites bled on probing, with proximal sites showing higher prevalence of both plaque and mucositis than buccal/lingual sites (Table 3).

No implant exhibited mobility. The mean probing depth varied from 3.0 mm (0.8) at buccal implants sites to 3.8 mm (1.0) at proximal sites. About 80% of all buccal and lingual peri-implant sites had a probing depth of ⩽3 mm, while at proximal sites the corresponding frequency was 61%. A PPD value of ⩾6 mm was not found at any buccal/lingual sites but at 9% of the proximal implant sites (all with a PPD of 6 mm). The mean height of the keratinized mucosa at the buccal aspect of the implants was 2.9 mm (1.0), with 11% of the sites showing 1 mm, 21% 2 mm and 68% ⩾3 mm of keratinized mucosa.

Radiographic findings

Baseline

The cumulative percentage distribution of the implants with respect to the peri-implant bone level at baseline (crown placement) is presented in Fig. 3. The *marginal bone to implant contact level* was at this interval located on the average 1.0 mm (0.62) apical of the reference point on the implant. At 38% of the implants the marginal bone level was found to be ⩾1 mm apical of the reference point. Only about 18% of the implants were judged to have the *bone to implant contact level* at the marginal edge of the implant.

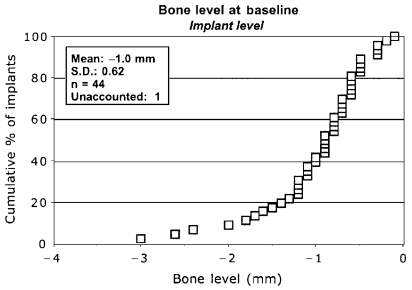

Fig. 3. Cumulative percentage distribution of implants according to mean peri-implant bone level at the time of insertion of the prosthetic crown (baseline).

Bone level change

The mean peri-implant bone level change that occurred during the 5 years of monitoring is described in Table 4 on the subject as well as on the implant level. During the first year there was on the average 0.06 mm (0.67) of marginal peri-implant bone loss on the subject and 0.02 mm (0.65) on the implant level ($p > 0.05$). During the subsequent 4 years the peri-implant bone level alterations were small with a calculated average annual loss of 0.02 mm (0.22) on both subject and implant levels. Thus, the mean total bone level change over the 5-year interval amounted to − 0.14 and − 0.11 mm, respectively, at the two levels of analysis ($p > 0.05$).

Figures 4 (subject level) and 5 (implant level) present the cumulative percentage of subject/implants that exhibited varying amounts of bone level change during the 5 years of observation. Between baseline and year 1, one subject (one implant) was lost to follow-up. During this interval 58% of the subjects and 63% of the implants had not experienced bone loss while three subjects and three implants (7%) displayed a peri-implant bone loss of ⩾1 mm.

Between Baseline and 5 years, three subjects and four implants (including the implant that was removed) were lost to the radiographic follow-up (Figs 4 and 5). About 44% of the remaining subjects and 48% of the implants had experienced no bone loss when compared with baseline data. Furthermore, during the 5-year interval five subjects (14%) and five implants (13%) exhibited a bone level reduction that was ⩾1 mm.

Smokers versus non-smokers

No statistically significant difference in bone level change was observed between smokers and non-smokers (Fig. 6). During the 5 years of monitoring, none of the smokers exhibited a peri-implant bone loss that exceeded 0.5 mm, whereas eight (30%) of the non-smokers demonstrated this amount of bone level change.

The binary logistic regression model, based on the case of a ''*bone loss of* > 0.5 *mm*'' between baseline and 5 years, revealed the best model fit when the factors gender, smoking habits and implant length were included as explanatory variables ($R^2 = 0.35$). However, only ''*implant length*'' was statistically significant ($p = 0.019$) and showed that the likelihood of finding a site with bone loss of > 0.5 mm increased with increased implant length.

Discussion

The results of the present 5-year prospective clinical trial demonstrated that

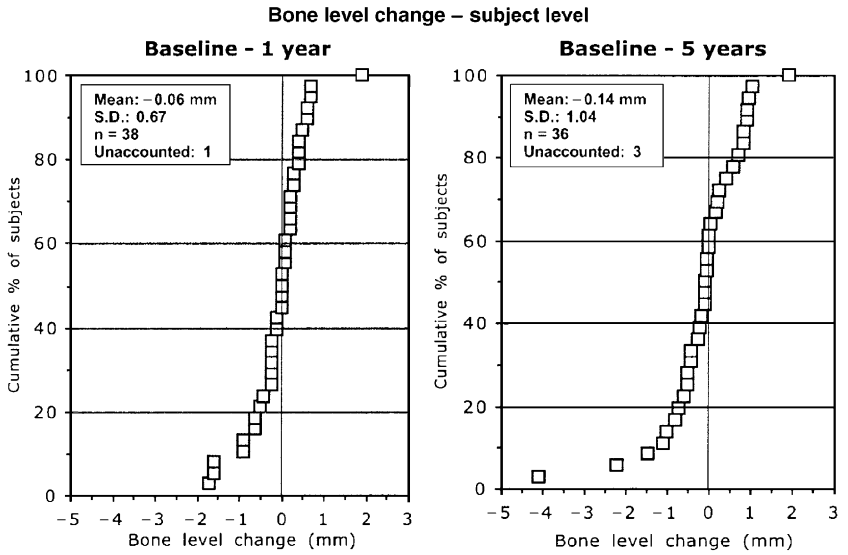

Fig. 4. Cumulative percentage distribution of the subjects according to mean peri-implant bone level change between baseline and 1 and 5 years, respectively.

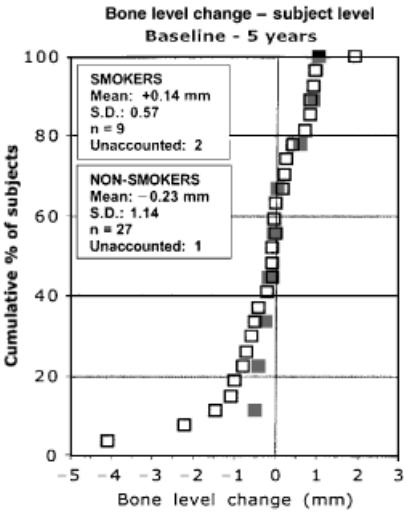

Fig. 6. Cumulative percentage distribution of smokers (red) and non-smokers (open blue) according to mean peri-implant bone level change during 5 years.

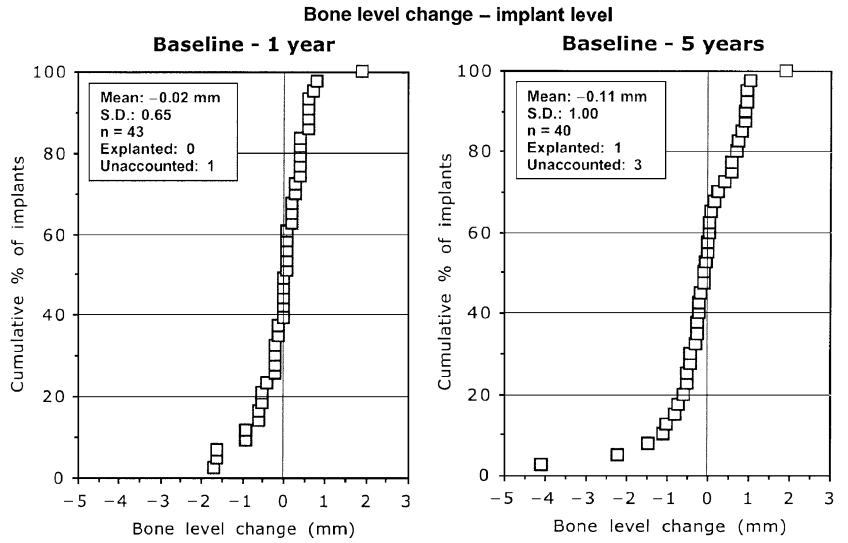

Fig. 5. Cumulative percentage distribution of the implants according to mean peri-implant bone level change between baseline and 1 and 5 years, respectively.

the bone level change that occurred at implant-supported single-tooth restorations with the Astra Tech® implant system were minimal during the first year of function as well as annually thereafter. Further, the implant failure rate was low, resulting in an overall survival rate of 97.4%, and a low incidence of technical complications.

According to Albrektsson & Isidor (1994) the criteria of success of an implant system demand an average marginal bone loss of less than 1.5 mm during the first year after insertion of the prosthesis and thereafter $\leqslant 0.2$ mm annual bone loss, i.e. a maximum of 2.3 mm bone loss after 5 years in function. In the present study, the average bone level change during the first year amounted to 0.06 mm and after 5 years to 0.14 mm. Hence, it is reasonable to conclude that the use of the Astra Tech® ST implant for single-tooth replacement was highly successful. Furthermore, applying the same criteria (Albrektsson & Isidor 1994) to the individual implant, only one implant exhibited bone loss >2.3 mm and thus failed to meet the criteria of ''success''. In this context, however, it must also be recognized that approximately 50% of the implants demonstrated no radiographic bone loss during the 5 years of observation (Fig. 7). Indeed, 11 implants (28%) presented at 5 years with an improved (>0.5 mm) bone height when compared with baseline values (Fig. 5). This favourable outcome with regard to the maintenance of the bone support at the Astra Tech® ST implant corroborates findings reported by others (Karlsson et al. 1997, Palmer et al. 2000, Norton 2001) and was attributed mainly to the presence of micro-threads in the conical, marginal part of the implant (Norton 1998, Hansson 1999). Thus, findings from similar studies in which the corresponding part of the implants used was non-threaded (e.g. Quirynen et al. 1992, Engquist et al. 1995, Malevez et al. 1996) disclosed that pronounced marginal peri-implant bone loss occurred during follow-up. Another difference between the current implant system and the implants used in the studies referred to is related to the topography of the surface. The implants used in the present study were designed with a modified, i.e. roughened surface (TiOblast®), while the implants used by e.g. Quirynen et al. (1992) and Engquist et al. (1995) had a machined surface topography. It may be argued, however, that differences in surface topography of the Astra Tech® implants may not necessarily play a decisive role for the maintenance of the marginal bone level during function. Thus, recent randomized studies in which Astra Tech® implants with identical geometry but with different surface characteristics –

machined and roughened – were compared, failed to document that the surface properties influenced bone level change during a 5-year period of monitoring (Gotfredsen & Karlsson 2001, Wennström et al. 2004). Whether the combination of micro-threads and roughened surface in the marginal part of the implant might have possessed a synergistic effect on the long-term stability of the peri-implant bone level in the current study cannot be determined but needs to be evaluated in future clinical studies.

The radiographic bone-to-implant contact level was at the time of crown placement (4–7 months after implant insertion) located apical to the marginal edge of the implant in the majority of the cases. In this context it must be realized that about one-third of the implants following insertion exhibited a facial bone dehiscence that was between 0.5 and 6 mm deep. Bone dehiscence defects are not likely to become resolved with bone formation (Dahlin et al. 1991, Schropp et al. 2003a), but may rather induce a circumferential bone remodelling in order to level out discrepancies in the bone-to-implant contact at different aspects around the implant (Carmagnola et al. 1999, Cardaropoli et al. 2003). Such bone remodelling may in the radiograph manifest itself as a reduced proximal bone level.

The majority of the implant sites showed, at 5 years, a probing depth of $\leqslant 3$ mm. Deeper probing depths were predominantly found at proximal sites of implants that had been inserted deep in relation to the bone level at neighbouring tooth surfaces, and was not associated with peri-implant bone loss or peri-implantitis lesions. The implant with the most pronounced longitudinal bone loss (4.1 mm; Fig. 8) was inserted 2 months following tooth extraction. This site had a thin alveolar ridge (4–5 mm) and following implant place-

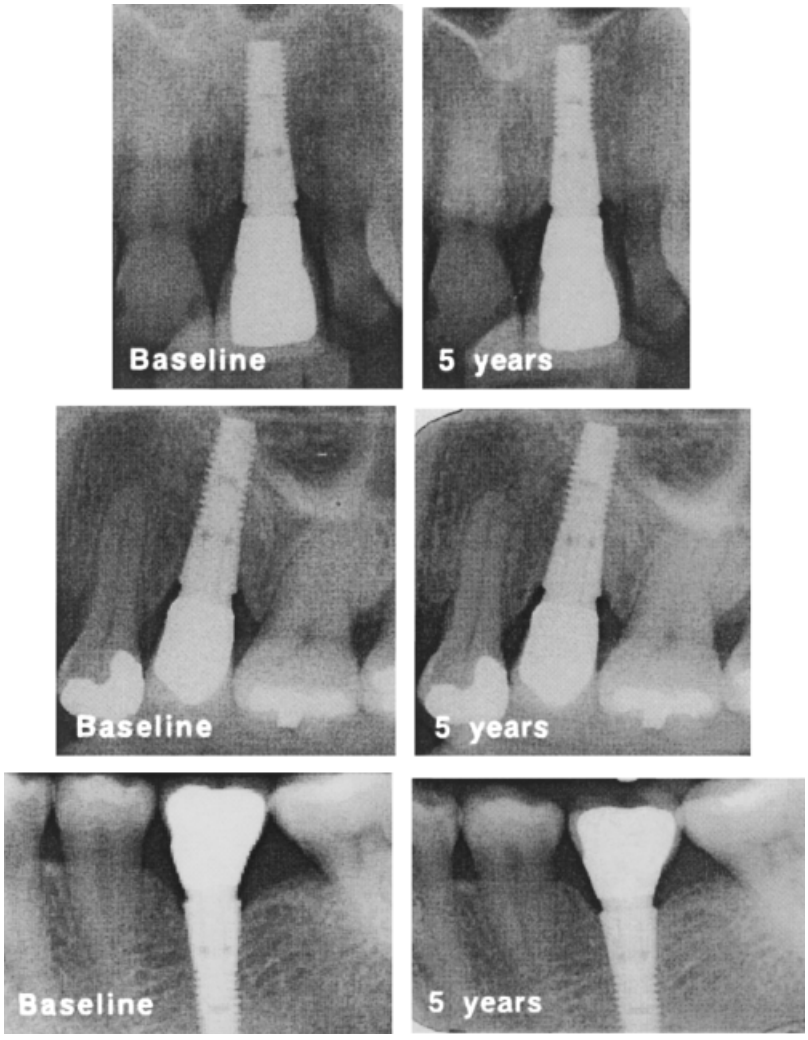

Fig. 7. Radiographic illustrations of three cases with implant placed in incisor, premolar and molar regions. Baseline (crown placement) and 5 years of follow-up.

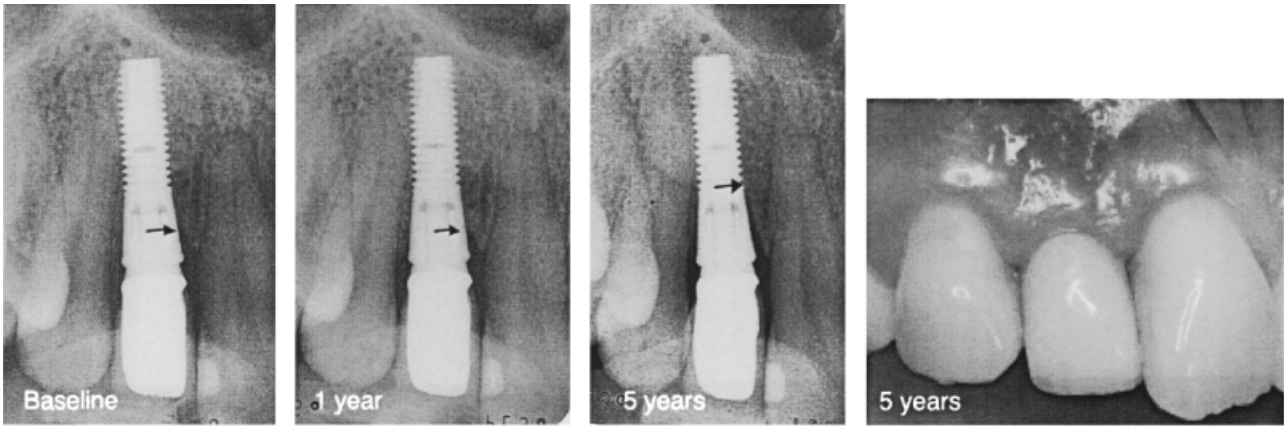

Fig. 8. Clinical and radiographic illustrations of the case with the most pronounced radiographic bone change. Baseline (crown placement), 1 and 5 years of follow-up.

ment, bone dehiscences of about 2 mm occurred both buccally and lingually. At all annual examinations, the mesial, distal, buccal and lingual probing depth at this implant was $\leqslant 3$ mm and no clinical signs indicated that the implant was exposed to excessive loading. It may be speculated therefore that the interpretation of the radiographs from this particular site as showing extensive loss of bone-to-implant contact may instead be the result of remodelling including resorption of the bone and the replacement of hard tissue with a long zone of connective tissue integration (PPD 3 mm). This hypothesis is supported by data reported from clinical and experimental studies on bone healing following tooth extractions (e.g. Pietrokovski & Massler 1967, Johnson 1969, Schropp et al. 2003b, Araújo & Lindhe 2005). Thus, Schropp et al. (2003b) reported from a study in humans that marked dimensional changes of the alveolar ridge will take place following single tooth extraction and that hard tissue remodelling may progress over a period of at least 12 months, resulting in marked reduction of the buccal–lingual thickness of the ridge.

Smoking is regarded as a risk factor for progressive loss of peri-implant bone and increased implant failure rate (for review see Bain 2003). In the current prospective study, however, such a relationship could not be confirmed. In fact, a ''*bone loss of* >0.5 *mm*'' was not observed in any of the smokers, while the incidence of this amount of bone loss was 30% among non-smokers. It must be recognized, however, that the study sample did not include heavy smokers (>20 cigarettes/day).

Implant length was the only factor that was identified in the logistic regression model as a significant predictor of a 5-year peri-implant ''*bone loss of* >0.5 *mm*''. Any rationale explanation for why an increased implant length entailed higher risk for bone loss is difficult to present, but a similar finding was reported by Naert et al. (2001) in a study on factors influencing the marginal bone stability around implants in the treatment of partial edentulism.

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