Implant Treatment with Fixed Prostheses in the Edentulous Maxilla. Part 1: Implants and Biologic Response in Two Patient Cohorts Restored Between 1986 and 1987 and 15 Years Later

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Purpose: Implant treatment has been performed for more than 45 years, but there is still limited knowledge on how treatment outcomes are changing over time. The aim of this study was to report and compare the treatment outcomes of two patient cohorts from the same clinic, rehabilitated with fixed implant prostheses in the edentulous maxilla between 1986 and 1987 (early) and 2001 to 2004 (late). ***Materials and Methods:*** The early group included 76 edentulous patients who were consecutively provided with 450 turned Brånemark System implants; the late group included 109 edentulous patients provided with 360 turned and 310 TiUnite Brånemark System implants. Both groups were followed and evaluated clinically and radiographically for 5 years according to similar protocols. ***Results:*** Altogether, 37 patients (20%) were lost to follow-up over 5 years; more patients were noncompliant in the late group ($P < .05$). The 5-year overall implant cumulative survival rates were 93.4% and 97.3% for the early and late groups, respectively. In the early group, significantly more turned implants failed before prosthesis insertion compared to the outcome of TiUnite implants in the late group ($P < .05$). Mean bone loss was comparable for the early and late groups during the 5 years of follow-up (0.5 ± 0.46 and 0.7 ± 0.76 mm, respectively), but more patients presented at least 1 implant with more than 2 mm of bone loss during the follow-up period in the late group ($P < .05$). Mucosal hyperplasia and inflammation showed a trend of higher frequency at implants in the early group of patients ($P > .05$). ***Conclusion:*** Implant treatment was more predictable before loading in the late group of patients, related to the change in the implant surface ($P < .05$). On the other hand, it was observed that the prevalence of patients with more bone loss at at least 1 implant (> 2 mm) was higher in the late group ($P < .05$). This could possibly be attributed to a more bioactive implant surface and shorter healing period before implant surgery in the late group. *Int J Prosthodont 2011;24:345–355.*

The first edentulous patients were treated with fixed prostheses supported by osseointegrated implants in 1965.[1] Following these original patients, long-term follow-up studies have shown good results with few severe problems.[2–9] However, long-term studies may involve treatment problems and complications resulting from formerly used techniques and components, and present levels of knowledge and clinical protocols are not necessarily the same as when the studies were initiated. Even though the biologic principles for osseointegration are unchanged, one must consider that increased knowledge (eg, changed surgical techniques and implant designs) makes it difficult to compare "old" data with the present. As a result of favorable animal studies completed over a decade ago,[10–13] implants with medium-rough surfaces are dominant today, replacing the older turned implants. Accordingly, implants of today differ from "yesterday's implants," and it can be argued whether data based on long-term studies are comparable with the clinical performance that could be expected from more recent techniques and materials.

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Table 1 Distribution of Patients with Regard to Bone Quality and Quantity at Implant Placement in the Early and Late Patient Groups

	Bone quantity* (early/late)					
Bone quality*	A	B	C	D	E	Total
1	0/0	0/0	1/0	0/0	0/0	1/0
2	0/1	3/19	2/8	0/1	0/0	5/29
3	3/0	21/23	28/38	3/6	1/1	56/68
4	1/0	1/3	6/8	3/1	1/0	12/12
Total	4/1	25/45	37/54	6/8	2/1	74†/109

*Determined according to the Lekholm and Zarb[19] classification.
†Information not available for two patients.

The purpose of this study was to report implant survival rates and patterns of implant complications and bone loss in two groups of patients rehabilitated with routine implant-supported fixed prostheses in edentulous maxillae between 1986 and 1987 and close to 15 years later at the same clinic (Brånemark Clinic, Göteborg, Sweden). The hypothesis was that changes in the clinical protocol and implant components over a 15-year period would improve the clinical results and reduce failure rates and problems related to bone and mucosal health.

Materials and Methods

The present study covers two groups of patients consecutively provided with fixed prostheses supported by implants in the edentulous maxilla at one clinic (Brånemark Clinic) from January 1986 to December 1987 and from January 2001 to November 2004. The first group of patients (early group) has been accounted for in earlier publications.[14–16] The second group (late group) is as accounted for in the present study, followed by a publication covering the prosthetic aspects of the two groups.[17] The design of the study is retrospective, but strict clinical protocols with similar follow-up procedures may allow for comparisons between the two groups, comparable to a "retro-prospective" study.[18]

Patient Groups

Inclusion and exclusion of patients as well as number, age, and sex of the included patients have been presented in more detail in other publications.[14–17] In brief, a total of 76 consecutively treated patients with a mean age of 60.1 years (standard deviation: 11.60) at first surgery were included in the early group. A corresponding number of 109 consecutive patients with a mean age of 65.1 years (standard deviation: 11.28) were included in the late group. The difference in mean age between the groups was significant ($P < .05$).[14–17]

Thirty-five (48%) and 56 (51%) patients reported no general health problems or use of medication in the early and late groups, respectively, and smoking habits were reported for 61.8% of patients in the early group and 51.0% of patients in the late group.[14–17]

Implant Surgery

Bone quality and resorption of the treated arches were classified in both groups at the time of first surgery according to the criteria described by Lekholm and Zarb[19] (Table 1).

Before implant surgery, routine postextraction healing periods of 3 or 6 to 8 months were used, depending on the amount and size of the extraction defects. However, a majority of patients in both groups were completely edentulous when referred to the clinic. Implant placement in both groups was based on a two-stage standard surgical procedure, with an average healing time of 5 to 8 months between implant surgery and abutment connection.[20] Some variations in the surgical protocol took place between the two inclusion periods, ie, implants with turned surfaces were solely used in the early group and a gradual change toward the TiUnite surface (Nobel Biocare) was at hand in the late group. The vestibular flap incision technique in the early group was changed to a crestal one in the late group. Further, while aiming for a more parallel implant positioning in the early group, nonparallel and thus longer implants were used in the late group, requiring angulated abutments more often.[21,22]

In total, 450 turned titanium Brånemark System implants (Nobel Biocare) were placed in the early group of patients[14–16]; 670 Brånemark System implants were placed in the late group, of which 360 and 310 had turned and TiUnite surfaces, respectively (Table 2). The TiUnite implant surface was of the original design, provided with a roughness gradient that resulted in a lower Sa value[11] in the coronal portion (smoother surface) and a higher Sa value[11] in the apical portion

(rougher surface). In the late group, the first 46 patients received only turned implants. An intermediate group of patients (n = 18) primarily received implants with turned surfaces, but TiUnite implants were used in more compromised sites presenting a more loose bone texture.[23] The remaining 45 patients received only TiUnite implants.

The objective was that at least 6 implants should be placed in the edentulous maxilla during both periods. One patient was provided with 8 implants (1.3%), 5 patients were provided with 7 (6.6%), 60 patients were provided with 6 (78.9%), 7 patients were provided with 5 (9.2%), and 3 patients were provided with 4 implants (3.9%) each in the early group. The corresponding distribution of implants per arch for the late group was 8 patients provided with 8 implants (7.3%), 6 patients provided with 7 (5.5%), 91 patients provided with 6 (83.5%), 2 patients provided with 5 (1.8%), and 2 patients with 4 implants each (1.8%).

Abutment surgery was performed after a healing period of 5 to 8 months. A surgical dressing (Coe-Pak Periodontal Dressing, GC) was applied to cover the operation field during healing in the early but not in the late group of patients.

Prosthetic Treatment

Definitive prosthetic treatment was completed according to a four- or five-appointment standard protocol, as described in detail in earlier publications.[14,24] Patients were restored with fixed, screw-retained, 10-unit prostheses. Prostheses were designed with either cast gold alloy or computer numeric controlled Procera titanium frameworks (Nobel Biocare) supporting artificial acrylic resin teeth.[25] Insertion of prostheses and final tightening of the locking screws were performed 2 to 6 weeks after abutment surgery.

Follow-up and Maintenance

All patients in both groups were scheduled for a similar follow-up protocol.[14–16] Accordingly, patients were scheduled for routine checkups after 1 and 5 years in function, but also individually recalled for closer checkups if indicated. However, all patients were encouraged to contact the clinic whenever they had problems with their prostheses.[14–16] Intraoral apical radiographs were taken on a routine basis at the Radiological Specialist Clinic, Public Dental Health Service, Göteborg, Sweden, at the time of prosthesis insertion and after 1 and 5 years in function. Radiologic data for the early group was also collected at 10 years to test the possibility to predict bone loss after the first 5 years.[16]

Table 2 No. of Implants Placed (Failed)

	Early	Late		
Implant length	Turned	Turned	TiUnite	Total
7 mm	111 (16)	7 (3)	14 (0)	21 (3)
8.5 mm	NA	7 (0)	13 (0)	20 (0)
10 mm	199 (13)	41 (1)	42 (0)	83 (1)
11.5 mm	0 (0)	29 (1)	48 (0)	77 (1)
13 mm	107 (0)	89 (5)	75 (2)	164 (7)
15 mm	28 (0)	106 (4)	88 (0)	194 (4)
18 mm	5 (0)	77 (0)	30 (0)	107 (0)
20 mm	0 (0)	4 (0)	NA	4 (0)
Total	450 (29)	360 (14)	310 (2)	670 (16)

NA = not available at time of surgery.

Data were collected from patient files, including all problems encountered during the follow-up period.[14–16] Bone levels were measured in relation to the implant threads to the closest 0.3 mm on the mesial and distal sides of the implant using the implant-abutment junction (IAJ) as a reference. A mean value between the mesial and distal measurements was used for each implant. Bone loss was calculated as the difference between mean bone levels around the implant at different checkup appointments.

According to the surgical protocol, all implants were inserted in contact with bone along their entire length (from head to apex), measured from the implant radiographic reference point (0.8 mm apical to the IAJ). As a result of this procedure, the "effective length" of implant-bone contact could be calculated from the reference point to the apex of the implant. Thus, bone loss could also be estimated corresponding to one third or half of this "effective length," ie, bone loss of one third of a 7-mm implant would be 2.1 mm and that for an 18-mm implant would be 5.7 mm. The corresponding amount of bone loss reaching half of the "effective length" of the implant would be 3.1 mm and 8.6 mm for the same implant sizes, respectively.

Since no prosthesis was removed on a routine basis to confirm individual implant stability after 5 years, only survival rates are used in the present study. Surviving implants were those still in function without symptoms of pain or severe problems, such as infection in combination with pus and rapid bone loss.

Statistical Analysis

Descriptive statistics and conventional life table analysis showing prosthesis cumulative survival rates (CSRs) were used in the present study. Differences

Table 3 Life Table of No. of Implants in the Early and Late Groups of Patients

	Early				Late			
	Implants	Dropout	Failure	Implant CSR (%)	Implants	Dropout	Failure	Implant CSR (%)
Surgery	450	0	0	100.0	670	0	0	100.0
Abutment	435	0	15	96.7	662	0	8	98.8
1 y	406	20	9	94.6	651	11	0	98.8
2 y	401	4	1	94.4	566	83	2	98.5
3 y	377	21	3	93.7	556	9	1	98.3
4 y	359	18	0	93.7	511	43	2	97.9
5 y	348	10	1	93.4	508	0	3	97.3
Total	348	73	29	93.4	508*	146	16	97.3

CSR = cumulative survival rate.
*Two patients were examined only clinically after 5 years, without radiographs.

between groups of patients were tested with regard to distributions using the chi-square test and with regard to mean values using the Student *t* test.

Overall statistical significance was set at 5%, and statistical comparisons were only performed on the patient level. Statistical tests were used with caution to limit problems with mass significance, avoiding testing for statistical differences in the material when no clear difference was indicated. Still, several individual statistical tests were performed in the present study (10 tests). To avoid false positive statistical results because of mass significance and to maintain an overall 5% level of significance, a correction of the *P* value was performed according to Bonferroni to a nominal level of $P < .005$ for the individual test.

Results

Patients Lost to Follow-up

Altogether, 12 (15.8%) and 25 (22.9%) patients were lost to follow-up and withdrawn during the 5-year follow-up period, incorporating 73 and 141 implants, respectively (Table 3). With the exclusion of 8 and 6 deceased patients, the 5-year dropout rate was 5.3% and 17.4% for the early and late patient groups, respectively. Reasons for the withdrawal of the remaining patients were (early, late): noncompliance (n = 1, n = 14), health problems (n = 1, n = 3), moved from the area (n = 2, n = 1), and controls at other clinics (n = 0, n = 1). More patients were noncompliant in the late group; however, this did not reach a significant level when adjusted for mass significance ($P > .05$). Another 2 patients were examined clinically in the late group, but they were not examined radiographically. Accordingly, 84 patients were followed clinically, but only 82 patients underwent radiographic examination after 5 years in the late group.

Implant Surgery

The number of patients treated with implants within the first year after final tooth extraction was 6 (7.9%) and 51 (46.8%) in the early and late groups of patients, respectively ($P < .05$).

Proportions of arches with more severe bone resorption (grade C and D, Table 1) were comparable for both groups (10.5% and 8.3%). However, 40 patients (52.6%) were provided with at least one short implant (< 10 mm) in the early group compared with only 25 patients (22.9%) with at least one short implant in the late group ($P < .05$). Regarding jaw bone quality, the overall majority of patients in both groups were assigned to Class 3, while proportionally more patients in the early group represented Class 4 (soft bone).

Implant Failures

Altogether, 29 implants (6.4%) in 20 patients (26.3%) were found to be mobile and removed during the 5-year follow-up period in the early group of patients (Tables 2 and 3). Fifteen of these implants (3.3%) were lost before prosthesis placement in 14 different patients (18.4%). Thereafter, 14 loaded implants were removed during the following 5 years in 10 patients. The 5-year implant CSR was calculated to be 93.4% in this group (Table 3), and only 7-mm (n = 16) and 10-mm (n = 13) implants were lost (Table 2). In the early group, 3 patients lost more than 1 implant each (n = 7) after prosthesis placement; 2 of these patients lost their fixed prostheses and resumed wearing removable dentures supported by the remaining implants.

In the late group, 16 implants (2.4%) in 13 patients (11.9%) failed and were removed during the 5-year follow-up period (Tables 2 and 3). Eight of the failed

Table 4 Mean Marginal Bone Level (mm) in Relation to IAJ

	Early			Late		
	Baseline	1 y	5 y	Baseline	1 y	5 y
No. of patients	76	71	62	104	97	82
No. of implants	431	402	350	634	590	499
Mean marginal bone level (SD)	1.4 (0.52)	1.8 (0.60)	2.0 (0.58)	1.5 (0.59)	1.8 (0.66)	2.2 (0.81)

IAJ = implant-abutment junction; SD = standard deviation.

Table 5 Distribution of Individual Implants (%) at Each Bone Level Throughout the Follow-up Period

	Early			Late		
Bone level to IAJ	Baseline	1 y	5 y	Baseline	1 y	5 y
0.0–0.8 mm	168 (39.0)	65 (16.2)	47 (13.4)	291 (45.9)	176 (29.8)	97 (19.4)
0.9–1.9 mm	202 (46.9)	208 (51.7)	163 (46.6)	220 (34.7)	222 (37.6)	185 (37.1)
2.0–2.5 mm	37 (8.6)	77 (19.2)	87 (24.9)	74 (11.7)	102 (17.3)	101 (20.2)
2.6–3.1 mm	13 (3.0)	28 (7.0)	35 (10.0)	29 (4.6)	59 (10.0)	49 (9.8)
3.2–3.7 mm	5 (1.2)	14 (3.5)	11 (3.1)	13 (2.1)	18 (3.2)	32 (6.4)
> 3.7 mm	6 (1.4)	10 (2.5)	7 (2.0)	7 (1.1)	13 (2.2)	35 (7.0)

First, second, third, and fourth threads are placed 1.9, 2.5, 3.1, and 3.7 mm below the IAJ, respectively.

implants (all with turned surfaces) were early failures (1.2%) in 7 patients (6.4%) and removed before prosthesis placement. The remaining 8 implants were removed during function, resulting in a 5-year implant CSR of 97.3% for the late group of patients (Table 3). Fourteen of the failing implants had turned surfaces (11 patients), and 2 had TiUnite surfaces (2 patients). The two TiUnite implants were still osseointegrated and stable but were removed because of severe marginal bone loss at the termination of the study. Implant failures in the late group were predominately seen in implants longer than 10 mm (n = 12, Table 3).

Fewer patients lost implants before loading in the late group of patients. Differences in the early implant failure rates, ie, implants lost before prosthesis placement, reached statistically significant levels when comparing patients with only TiUnite implants (n = 45) and the early group of patients ($P < .05$). When comparing early failures in patients with only TiUnite implants with those of patients provided with only turned implants in the late group (n = 46), the difference did not reach a significant level when considering mass significance ($P > .05$). Furthermore, no significant difference was observed between early failures in the early group of patients (n = 76) and early failures in patients in the late group with only turned implants (n = 46, $P > .05$).

Prosthesis Survival and Implant Complications

Two fixed prostheses were lost in the early group (CSR: 97.2%), while all prostheses survived in the late group (CSR: 100%) throughout the 5 years. Fewer patients had their prostheses temporarily removed for adjustments and problems in the late group. These adjustments were basically a result of implant failures, veneer fractures, and diction.

No implants or abutment screws fractured during the follow-up period. Mucosa hyperplasia and inflammation at the implants showed an insignificant trend of a higher frequency at implants in the early group ($P > .05$); fistulas were only reported at implants in the early group (n = 11).

Radiographs

Distance of mean marginal bone levels in relation to the IAJ increased from baseline to the termination of the study in both groups (Table 4). No obvious differences in mean levels were observed between groups, although significantly more patients had at least one implant with the bone level below the third implant thread (> 3.1 mm) at the termination of the study in the late group of patients ($P < .05$, Tables 5 and 6).

A similar pattern of mean bone loss was also shown in both groups of patients during the follow-up (Tables 7 and 8). Altogether, 5 and 25 implants presented bone loss of more than 2 mm during the

Table 6 No. of Patients Presenting Implants with a Bone Level of ≥ 3 Threads to the IAJ (> 3.1 mm)

	Early			Late		
Implants	Baseline	1 y	5 y	Baseline	1 y	5 y
0	71	65	56	90	79	48
1	4	4	5	10	12	17
2	1	1	1	3	2	8
3	0	0	0	0	1	4
> 3	0	1	0	1	3	5

IAJ = implant-abutment junction.

Table 7 Mean Marginal Bone Loss (mm) During Different Periods of Follow-up

	Early			Late		
	0–1 y	0–5 y	1–5 y	0–1 y	0–5 y	1–5 y
No. of patients	71	62	61	95	78	76
No. of implants	403	351	345	578	474	461
Mean marginal bone loss (SD)	0.4 (0.31)	0.5 (0.46)	0.1 (0.39)	0.3 (0.55)	0.7 (0.76)	0.4 (0.51)

SD = standard deviation.

Table 8 Distribution of Implants (%) with Regard to Bone Resorption During Different Periods of Follow-up

	Early			Late		
Bone loss	0–1 y	0–5 y	1–5 y	0–1 y	0–5 y	1–5 y
< 0.0 mm*	40 (9.9)	46 (13.1)	93 (27.0)	55 (9.5)	43 (9.1)	38 (8.2)
0.0 mm	106 (26.3)	67 (19.1)	101 (29.3)	315 (54.5)	176 (37.1)	249 (54.0)
0.1–0.6 mm	129 (32.0)	89 (25.4)	102 (29.6)	74 (12.8)	76 (16.0)	68 (14.8)
0.7–1.2 mm	104 (25.8)	104 (29.6)	39 (11.3)	74 (12.8)	90 (19.0)	67 (14.5)
1.3–1.8 mm	14 (3.5)	34 (9.7)	7 (2.0)	31 (5.4)	40 (8.4)	19 (4.1)
1.9–2.4 mm	9 (2.2)	8 (2.3)	2 (0.6)	18 (3.1)	20 (4.2)	7 (1.5)
2.5–3.0 mm	1 (0.2)	1 (0.3)	1 (0.3)	5 (0.9)	12 (2.5)	5 (1.1)
> 3.0 mm	0 (0.0)	2 (0.6)	0 (0.0)	6 (1.0)	17 (3.6)	8 (1.7)

*Increase in bone level between two registrations.

first year of function in the early and late groups, respectively. The corresponding numbers of implants for the period from baseline to 5 years were 7 and 45 implants. Significantly more patients in the late group presented at least 1 implant with more than 2 mm of bone loss during 5 years of follow-up ($P < .05$, Table 9). Considering bone loss in relation to the entire implant length, few implants lost more than one third or half of the bone support (Table 9).

When comparing values of mean marginal bone loss for patients receiving either only turned or only TiUnite implants in the late group, only small differences were observed (Tables 10 and 11). Patients with at least one implant with more than 2 mm of bone loss during the period from baseline to termination of the study showed a trend of higher prevalence for those who received TiUnite implants as compared to patients provided with only turned implants (Table 12). This difference was not significant after correction for mass significance ($P > .05$). No other obvious differences were observed between patients with turned and TiUnite implants in the late group or between patients with turned implants in the early and late groups.

Eighteen implants in the early group presented bone levels below the third thread of the implant (> 3.1 mm) at the termination of the study, as shown in Table 5. When considering radiographic data in the early group after 10 years, 12 of these implants were possible to follow-up with to the 10-year checkup. Of the 6 missing implants, 5 were lost to follow-up and 1 implant failed. Figure 1 shows that only 2 implants presented bone loss from 5 to 10 years of follow-up,

Table 9 Distribution of Patients and Implants with Bone Loss of > 2 mm and > 1/3 and > 1/2 of the Implant Effective Length

	Early			Late		
	0–1 y	0–5 y	1–5 y	0–1 y	0–5 y	1–5 y
> 2 mm bone loss						
0 implants	67	59	58	79	49	62
1 implant	3	0	3	10	19	11
2 implants	1	2	0	5	6	2
3 implants	0	1	0	0	3	1
> 3 implants	0	0	0	1	1	0
> 1/3 of effective length						
0 implants	71	60	61	92	70	72
1 implant	0	1	0	3	6	3
2 implants	0	1	0	0	2	1
> 1/2 of effective length						
0 implants	71	62	61	95	77	76
1 implant	0	0	0	0	1	0
2 implants	0	0	0	0	0	0

Table 10 Mean Marginal Bone Loss (mm) for Patients Provided with Only Turned (n = 46) and TiUnite surfaces (n = 45) in the Late Group

	Turned			TiUnite		
	0–1 y	0–5 y	1–5 y	0–1 y	0–5 y	1–5 y
No. of patients	38	34	32	41	27	29
No. of implants	235	210	198	244	160	172
Mean marginal bone level (SD)	0.3 (0.65)	0.5 (0.85)	0.3 (0.48)	0.4 (0.45)	0.9 (0.75)	0.5 (0.55)

SD = standard deviation.

Table 11 Distribution of Implants (%) with Regard to Bone Resorption for Patients Provided with Only Turned (n = 46) and TiUnite Surfaces (n = 45) in the Late Group

	Turned			TiUnite		
Bone loss	0–1 y	0–5 y	1–5 y	0–1 y	0–5 y	1–5 y
< 0.0 mm*	27 (11.5)	27 (12.9)	22 (11.1)	13 (5.3)	5 (3.1)	11 (6.6)
0.0 mm	137 (58.3)	89 (42.4)	111 (56.1)	135 (55.3)	62 (38.8)	90 (52.3)
0.1–0.6 mm	22 (9.4)	37 (17.6)	32 (16.2)	36 (14.8)	12 (7.5)	14 (8.1)
0.7–1.2 mm	29 (12.3)	29 (13.8)	19 (9.6)	34 (13.9)	41 (25.6)	38 (22.1)
1.3–1.8 mm	9 (3.8)	11 (5.2)	5 (2.5)	13 (5.3)	20 (12.5)	12 (7.0)
1.9–2.4 mm	5 (2.1)	6 (2.9)	3 (1.5)	9 (3.7)	7 (4.4)	2 (1.2)
2.5–3.0 mm	3 (1.3)	3 (1.4)	2 (1.0)	1 (0.4)	6 (3.8)	2 (1.2)
> 3.0 mm	3 (1.3)	8 (3.8)	4 (2.0)	3 (1.2)	7 (4.4)	3 (1.7)

*Increase in bone level between two registrations.

and the remaining 10 implants presented an improved bone level at the 10-year examination. When selecting implants presenting bone levels below the third thread after 10 years in function (18 implants), it can be noticed that most implants presented a better situation than the third thread at the 5-year examination (Fig 2).

Table 12 Distribution of Patients and Implants with Bone Loss of > 2 mm and > 1/3 and > 1/2 of the Implant Effective Length with Respect to Turned and TiUnite Surfaces in the Late Group

	Turned			TiUnite		
	0–1 y	0–5 y	1–5 y	0–1 y	0–5 y	1–5 y
> 2 mm bone loss						
0 implants	33	30	24	34	17	25
1 implant	2	1	6	5	5	2
2 implants	2	1	1	2	3	2
3 implants	0	1	0	0	2	0
> 3 implants	1	1	1	0	0	0
> 1/3 of effective length						
0 implants	37	31	30	40	23	28
1 implant	1	3	2	1	2	0
2 implants	0	0	0	0	2	1
> 1/2 of effective length						
0 implants	38	34	32	41	26	29
1 implant	0	0	0	0	1	0
2 implants	0	0	0	0	0	0

Discussion

Altogether, 73 (16.2%) and 141 (21.0%) implants in 12 (15.8%) and 24 (22.0%) patients were lost to follow-up during 5 years in function, respectively (Table 3). The ratio of noncompliant patients was higher in the late group ($P < .05$). This could be explained by observations that early pioneer groups of patients are more satisfied and attend more check-up maintenance than later routine groups of patients[6,10] as well as the higher age at inclusion for the patients in the late group. Still, the ratio of withdrawals was below 25% during follow-up, which has been reported to be a critical level for statistical reliability when interpreting implant data in follow-up situations.[27,28] Accordingly, even though withdrawals have been reported to present somewhat higher levels of failures and complications,[6,29] the present data could be considered viable and useful for analyzing implant failures and complications over time.

In the present study, it can be observed that the surgical approach has changed over time, eg, placing longer implants in the late group of patients (see Table 2) with approximately the same amount of jaw bone resorption as observed in the early group (see Table 1). The rationale for this modification was based on earlier observations that shorter implants (< 10 mm) presented higher failure rates than longer implants.[30] However, even though this change reduced the number of failures of short implants from 14.4% (16 of 111) in the early group to 7.3% (3 of 41) in the late group, the overall implant failure rates were comparable, even with an observed increase in failures of long implants from 0% to 2.3% (11 of 469) in the late group (see Table 2). When first considering the change of the implant surface from turned to TiUnite, it was possible to show a significant reduction of early implant failures in the patient populations ($P < .05$). Accordingly, it is tempting to suggest that implant surface has a higher impact on early failure rates, as compared to exchanging short parallel with longer nonparallel implants. During the phase of functional loading, ie, after prosthesis placement, no significant difference in implant failure could be demonstrated comparing turned implants in early and late groups or turned implants compared to TiUnite implants, even though the TiUnite surface indicated a better survival during this phase.

Research has indicated clearly that the roughness of the implant surface has an important impact on the early bone response in animals.[11] During the last decade, an obvious change in clinical use of implant surfaces from turned to medium-rough has taken place. The present study indicates evidence for such a change by confirming earlier animal studies showing significantly better early implant survival for the medium-rough TiUnite implant ($P < .05$). Similar observations

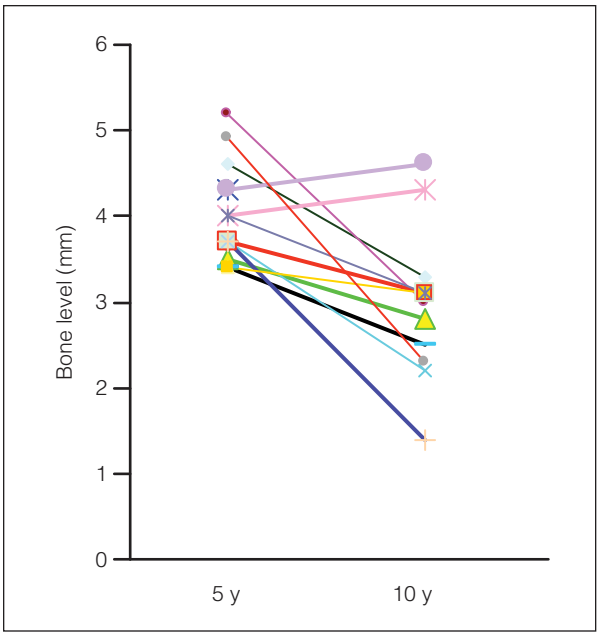

Fig 1 All implants with bone levels below the third thread (> 3.1 mm below the IAJ) after 5 years in function and followed for up to 10 years.[16] Notice the obvious trend of improved bone level from 5 to 10 years for most implants (n = 10). Of the 18 included implants at 5 years, only 12 were examined at 10 years; 5 implants were lost to follow-up and 1 implant failed.

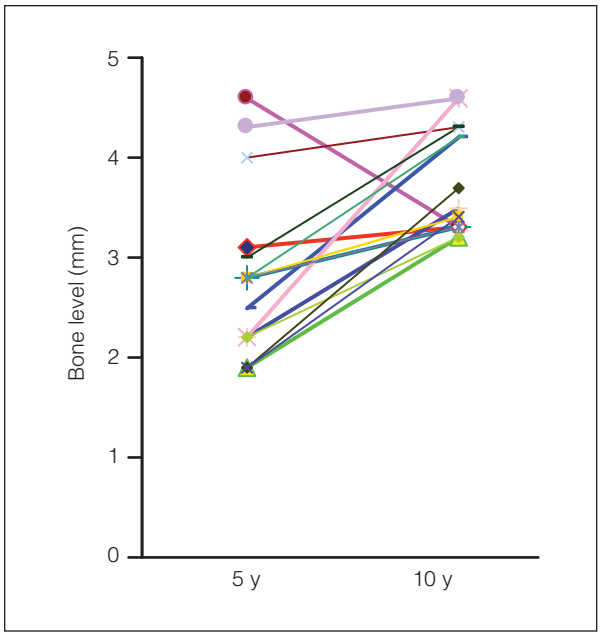

Fig 2 All implants with bone levels below the third thread (> 3.1 mm below the IAJ) after 10 years in function (n = 18).[16] Notice that most of these implants showed bone levels above the third thread of the implant at the 5-year examination.

have been reported in other studies.[23,31,32] However, based on animal studies, it has been suggested that a more bioactive (rough) implant surface may be more vulnerable to plaque accumulation and inflammation, resulting in more bone resorption.[33] This has not been confirmed in the clinical situation as yet, but data from available comparative studies indicate a consistent increase, although not statistically significant, in average bone loss for medium-rough implant surfaces during follow-up (Table 13).[23,33,34] This assumption is supported by the present observation that patients with TiUnite implants showed more implants with bone loss of > 2 mm, which could possibly be the same for the other groups in previous studies. [23,33,34] On the other hand, the use of a medium-rough implant surface increases the early survival rate, but those implants presenting more bone loss could possibly be those that would have been lost if turned surfaces had been used.

The reference for measuring bone levels has changed over the years. First, the radiographic reference point was used[35] successively and replaced by the IAJ, as used in the present study. Since the IAJ is placed 0.8 mm coronal to the radiographic reference point, all data on bone levels are affected by this change (Table 5), while data on bone loss, calculated from differences between bone levels, are unaffected. However, time of baseline radiographs in relation to the surgical intervention may also have an obvious impact on early bone loss.[31] Accordingly, to allow assessment of early changes of bone at implants, it is therefore recommended to report early bone levels as well as early bone loss and time from surgery to baseline radiographs.[31] In the present study, time between the second surgery and prosthesis placement was longer for the late group, shown by the slightly lower position of bone levels at the placement of prostheses but reached the same levels as the early group at the first annual examination (Table 4).

Also, bone loss over longer periods has been discussed in relation to treatment outcome, exemplified

Table 13 Reported Mean Marginal Bone Loss (mm) for Turned and Medium-Rough Implant Surfaces.

		Mean bone loss (0–5 y)*	
Study	Surface	Turned surface	Medium-rough surface
Gotfredsen and Karlsson[34]	TiOblast	0.2	0.5
Wennström et al[36]	TiOblast	0.3	0.5
Friberg and Jemt[23]	TiUnite	0.6	0.8
Present study	TiUnite	0.5	0.9

*Consistent, but not statistically significant, differences can be observed between mean bone loss at turned and medium rough surfaces during 5 years in function in all four studies.

by the effort to try to identify and include patients suffering from "peri-implantitis." This has been performed by selecting implants and patients presenting lower marginal bone levels or a certain amount of bone loss at follow-up.[36–39] The inclusion of these implants/patients is probably based on the assumption that they are suffering from a more severe problem and are considered to involve a higher risk for future inflammation and bone loss. However, to retrospectively identify implants with more than three threads of bone loss from first to fifth year of follow-up does not necessarily identify those implants that are at the highest risk for the most bone loss the following 5 years (Fig 1). Instead, implants with a better bone situation at 5 years are those that may show the most bone loss from 5 to 10 years of follow-up (Fig 2). This problem with measuring changes in relation to baseline has been discussed extensively in the periodontal literature and is referred to as a statistical problem with regression toward mean and mathematic coupling.[40–42]

Conclusions

The present study indicates that several changes have taken place in the surgical protocol, as well as in the design of the implants over the years. Present data showed significantly fewer patients with early implant failures when provided with a medium-rough surface ($P < .05$). However, since there were significantly more patients with medium-rough implant surfaces that presented at least one implant with more than 2 mm of bone loss during the follow-up period ($P < .05$), another long-term follow-up pattern for those implants could be considered. Still, more implants seem to integrate with medium-rough surfaces, and it cannot be known for certain that the implants with more bone loss in the late group would be those that would have been lost if provided with turned surfaces.

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Literature Abstract

Dental devices: Classification of dental amalgam, reclassification of dental mercury, designation of special controls for dental amalgam, mercury, and amalgam alloy. Final rule

The aim of this United States Federal Register report is to announce a final rule from the Food and Drug Administration (FDA) classifying dental amalgam, dental mercury, and amalgam alloy as Class II devices. These three devices are classified in a single regulation. Class II devices are those for which general controls alone are insufficient to assure safety and effectiveness, and additional existing methods are available to provide such assurances. Therefore, Class II devices are also subject to special controls in addition to the general controls of Class I devices. Based on the review of scientific evidence, the FDA found that firstly, probable benefits to health from the use of dental amalgam for its intended use and conditions for use, when accompanied by adequate directions and warnings against unsafe use, outweigh any probable risks; secondly, the scientific evidence adequately demonstrates the absence of unreasonable risk of illness or injury associated with the intended use of dental amalgam. The FDA has made the following conclusions: *(1)* exposure to mercury vapors from dental amalgam does not put individuals age 6 and older at risk for mercury-associated adverse health effects, *(2)* there is a paucity of studies that evaluate a link between dental amalgam and neurologic conditions, *(3)* existing data do not suggest that fetuses are at risk for adverse health effects due to maternal exposure to mercury vapors from dental amalgam, and *(4)* infants are not at risk for adverse health effects from breast milk of women exposed to mercury vapors from dental amalgam. The FDA acknowledges that some individuals have a known allergy to mercury, and recommends the following specific labels: *(1)* WARNING: CONTAINS MERCURY; *(2)* Warning: May be harmful if vapors are inhaled; *(3)* Precautions: Use with adequate ventilation and store in a cool, well-ventilated place; and *(4)* Contains [ ]% mercury by weight. It is noteworthy that the FDA concludes that dental amalgam remains a safe and reliable dental material, provided proper handling protocols are observed. This report also lends strong support against certain movements to ban the use of dental amalgam.

Food and Drug Administration, HHS. *Fed Regist* 2009;74:38685–38714. **References:** 89. **Reprints:** Michael E. Adjodha, Food and Drug Administration, Center for Devices and Radiological Health, 10903 New Hampshire Ave, Building 66, Room 2606, Silver Spring, MD 20993-0002 —*Elvin W.J. Leong, Singapore*