Clinical Evaluation of a Prospective Multicenter Study on 1-piece Implants. Part 1: Marginal Bone Level Evaluation After 1 Year of Follow-up

Kaj Finne, DDS[1]/Eric Rompen, DDS, PhD[2]/Joseph Toljanic, DDS[3]

Purpose: *The aim of the present investigation was to evaluate the marginal bone level after 1 year of follow-up of 1-piece implants after immediate provisional restoration fabrication.* ***Materials and Methods:*** *Patients received NobelDirect and NobelPerfect 1-piece implants (Nobel Biocare, Göteborg, Sweden) that were immediately restored and placed into function as part of a 3-year, multicenter investigation. Life table analysis was used for evaluation of implant cumulative survival rates. The Student* t *test (for dichotomous variables) and Pearson correlation (for continuous and ordered categorical variables) were used to estimate the influence of separate parameters on marginal bone.* ***Results:*** *Eighty-seven patients received 152 NobelDirect or NobelPerfect 1-piece implants. Of these, 81 patients returned for the 1-year follow-up and 21 for the 2-year follow-up. Three implants were lost, resulting in a cumulative survival rate of 97.9% after up to 2 years. The average marginal bone level at implant placement was 0.33 mm (SD 1.20, n = 141) superior to the reference point (lower edge of the implant collar). Marginal bone level was −0.77 mm (SD 1.33, n = 138) at 6 months and −0.98 mm (SD 1.38, n = 123) at 1 year. Average bone level at the 2-year follow-up was 0.17 mm (SD 1.20, n = 26). After 1 year of loading, bone level in the maxilla was more apical compared to that in the mandible (*P = .05*), and a positive correlation was found between bone level at placement and bone level at 12 months (*P = .008*). Shallow implant positioning resulted in less marginal bone remodeling compared to deep implant positioning.* ***Conclusion:*** *On the basis of this prospective multicenter study, stable marginal bone level and soft tissue support the hypothesis that the 1-piece implant has the capacity to preserve both hard and soft tissue.* Int J Oral Maxillofac Implants 2007;22:226–234

Key words: *bone level, immediate function, 1-piece dental implants, radiologic evaluation*

The original Brånemark dental implant was designed as a 2-piece implant to be used in a 2-stage treatment procedure. At the first-stage surgery, the implant was placed after raising a soft tissue flap, which was subsequently repositioned to cover the implant during healing. After a healing period, a new flap was elevated, and a transmucosal abutment was screwed onto the implant to allow prosthesis connection.[1]

In recent years, it has been demonstrated that the 2-stage procedure with a submerged healing period may not be required and that implants can be placed in a 1-stage surgical procedure with immediate prosthetic loading without compromising the osseointegration.[2–4]

In addition to osseointegration, soft tissue esthetics is key to successful implant treatment. It is often argued that optimal soft tissue integration requires minimal intervention during the integration process. Further, to obtain esthetically pleasing soft tissue, it is desirable to avoid manipulation of the soft tissue during and after initial healing, since such intervention may disrupt the soft tissue seal.[5] However, manipulation of the soft tissue is inevitable when the implants are placed according to a 2-stage surgical protocol, as abutment connection necessitates a second surgical intervention of the soft tissue. In addition, the 2-stage protocol usually involves the use of healing abutments. Such abutments are removed after soft tissue healing, and their removal may result in disruption of the tissue at the implant–soft tissue interface.

[1]Private Practice, Vasa, Finland.
[2]Professor, Department of Periodontology, University of Liege, Belgium.
[3]Professor, Department of Surgery, The University of Chicago, Illinois.

Correspondence to: Dr Kaj Finne, Tidens Tand, Sandögatan 24, FIN 651 00 Vasa, Finland. E-mail: k.finne@kolumbus.fi

Thus, it is feasible and, to maintain soft tissue esthetics, often preferable, to perform a 1-stage surgical procedure. However, if a 1-stage surgical procedure is carried out with immediate prosthetic loading using a 2-piece implant system, the abutments may be changed during the treatment period, before delivery of the definitive prosthesis. Therefore, a 1-piece implant design that combines the intraosseous threaded implant body, the transmucosal abutment, and the pillar for crown cementation in a single piece has been developed.

The aim of the present investigation was to evaluate the clinical performance of NobelDirect and NobelPerfect 1-piece implants after immediate provisional restoration and to evaluate changes in marginal bone level and esthetic outcome over 3 years. The hypothesis was that this 1-piece implant design would preserve the soft tissue seal with optimal esthetics and preservation of the marginal bone level. This article presents the marginal bone level after 1 year of follow-up.

MATERIALS AND METHODS

Study Components

A 1-piece implant design combining the intraosseous threaded implant body, the transmucosal abutment, and the pillar for crown cementation in a single piece (NobelDirect and NobelPerfect Onepiece, Nobel Biocare, Göteborg, Sweden) was evaluated in the present study. The abutment part of the implant may be prepared in situ, and it is possible to follow the individual anatomy of the soft tissue margin without violating the soft tissue seal by repeated changes of the abutment. This 1-piece implant design is available in 2 versions, 1 with a scalloped borderline of the TiUnite surface (Nobel Biocare), and 1 with a circular borderline of the TiUnite surface. Both versions are available in 3 diameters (3.5, 4.3, and 5.0 mm) and 3 lengths (10, 13, and 16 mm).

Study Protocol

This was an open, prospective investigation in which subjects missing at least 1 tooth in the maxilla or mandible who met the inclusion criteria were consecutively enrolled. The investigation was approved by the responsible institutional review boards/ethics committees. Healthy subjects with good oral hygiene for whom implant treatment using a 1-stage procedure with immediate provisional restoration was planned were eligible for the study. Other inclusion criteria were a stable occlusal relationship with no pronounced bruxism, sufficient bone volume for placing an implant or implants with a length of at least 10 mm, and a final tightening torque at implant placement of 35 to 45 Ncm. The implant site had to be free of infection and, in the case of immediate placement in extraction sockets, free of extraction remnants.

Exclusion criteria consisted of the following: *(1)* circumstances that could affect the subject's health or the subject's cooperation; *(2)* any disorders in the planned implant area, such as previous tumors, chronic bone disease, or previous irradiation; *(3)* angulation requirements of the restoration exceeding 10 to 15 degrees, *(4)* need for cantilevers, and *(5)* inability to provide informed consent.

The implants were placed according to the Nobel Direct Clinical Guidelines (Nobel Biocare clinical procedure and product catalog) in a 1-stage procedure with an immediate provisional restoration. If the planned prosthetic construction was to be supported by more than 1 implant, care was taken to place the implants parallel to one another. Either flapless placement or placement with a soft tissue flap was carried out. The flapless technique was performed with a tissue punch when a sufficient amount of fibrous mucosa was available. The provisional cemented restorations were made according to routine procedures. Functional occlusion was either avoided or was limited to light contact in central occlusion. After surgery, the subjects were provided with a home-care maintenance procedure and scheduled for postsurgical check-ups at 3 months, 6 months, and 1, 2, and 3 years. Replacement of provisional prostheses with definitive prosthetic restorations was performed on an individual basis.

The clinical evaluation at all follow-up visits, except for the 2-year follow-up, included assessment of the status of the peri-implant mucosa and the presence of plaque. The status of the mucosa was recorded as 0 for a normal mucosa, 1 for bleeding on superficial probing, and 2 for discoloration and spontaneous bleeding. Plaque status was recorded as 0 for no visible plaque and 1 for visible plaque. Implant or, when applicable, prosthetic stability was recorded at all follow-up visits as stable or unstable.

For evaluation of the papillae, Jemt's papilla index was used.[6] In short, this index consists of 5 scores, where 0 denotes the absence of a papilla, 1 denotes the presence of less than half of a papilla, 2 denotes the presence of at least half of a papilla (ie, a papilla that does not fully reach the contact point between the crowns), 3 denotes a papilla that fills the entire proximal space and is in good harmony with the adjacent papillae, and 4 denotes a hyperplastic papilla that covers too much of the implant restoration and/or adjacent tooth. Papillae were evaluated at implant placement (ie, placement of the provisional restoration), placement of the definitive restoration, and at the 3-year follow-up. All adverse events during the course of the study were carefully recorded.

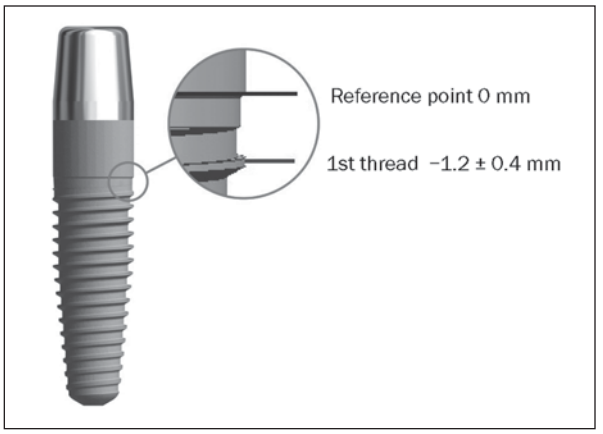

Fig 1 Illustration of the reference point used for the radiographic readings on a 1-piece implant (ie, the lower edge of the implant collar).

Radiographic Evaluation

Intraoral radiographs were made at implant placement, at the 6-month and 1-year follow-up visits, and yearly thereafter. Radiographs were made perpendicular to the implant with a long-cone parallel technique. Radiographs made at implant placement served as the baseline registration for evaluation of the marginal bone remodeling over the study period. The marginal bone level (ie, the position of the marginal bone as compared to a reference point on the implant) was evaluated. The reference point for the readings was the lower edge of the implant collar (Fig 1). The bone level apical or coronal to this point was recorded. An independent radiologist at Göteborg University, Sweden, examined all radiographs.

Implant Success and Failure Criteria

The criteria for success proposed by Albrektsson et al[7] were modified for use in this investigation. The success criteria used in the present study were as follows. An implant was regarded as "successful" when *(1)* there was no radiolucency around the implant; *(2)* there were no signs of infection, pain, or ongoing pathologic processes at the implant site; *(3)* the implant was restored and functionally loaded; and *(4)* the individual implant (in case of single-tooth restorations) or the prosthetic restoration (in the case of multiple implants supporting a partial or full-arch restoration) was stable. An implant was classified as "surviving" when it remained in the jaw and was functionally loaded but did not meet every criterion for success. A "failed implant" was an implant that had fractured beyond repair or could not be classified as a successful or surviving implant.

Statistical Analysis

The statistical evaluation included all data collected from the surgery and follow-up examinations. Life table analysis was used for evaluation of the cumulative success and survival rates of implants. The Student *t* test (for dichotomous variables) and Pearson correlation (for continuous and ordered categorical variables) were used to estimate the influence of each separate parameter on marginal bone level at 1-year of follow-up and on marginal bone remodeling between placement and 1-year of follow-up. Dependence of results within subjects was evaluated following conservative methods: The *P* values for the correlation and for the *t* tests were adjusted to individual level by multiplying the variances by the number of implants divided by the number of subjects (ie, by n_{impl}/n_{pat}). Using the adjusted variances, a more conservative method for the calculation of *P* values was applied. All tests were 2-tailed and conducted at the 5% significance level.

RESULTS

Patient Material

Five clinics were invited to participate in this study. However, 1 clinic was withdrawn for administrative problems. Between November 2003 and October 2004, 4 clinics consecutively included 87 subjects, 44 women and 43 men, with a mean age of 55 years (range, 23 to 83). Seventy-nine of the subjects were nonsmokers (91%). A total of 152 implants were placed within the study, 91 NobelDirect and 61 NobelPerfect 1-piece implants (Nobel Biocare), to support a total of 101 prosthetic restorations. The restorations were single-tooth (64), partial (35) or complete (2) restorations in the mandible. For specification of implant lengths and diameters, see Tables 1a and 1b. Implant distribution in bone quality and quantity is presented in Table 2, and implant distribution with respect to position is given in Table 3. The majority of the implants (86%) were placed in healed sites, while 14% were placed in extraction sockets. A flap was raised when placing 92 of the implants, while 60 implants were placed using a flapless technique. For 17 (11%) of the implants, local bone grafting was performed at implant placement. Forty implants required preparation of the implant before insertion of the provisional restoration, while 112 implants received a provisional restoration without preparation of the implant. All subjects received a provisional restoration on the day of surgery; 52% of the restorations were out of occlusion and the remaining 48% were in light centric occlusion.

At the time of final data analysis for this study, 81 subjects (93%) had attended the 1-year follow-up. Eighty subjects (corresponding to 94 restorations) had received a definitive prosthesis a mean of 4.7

Table 1a Specification of Implant Length and Diameter for the NobelPerfect 1-piece Implants

	Maxilla		Mandible	
	Placed	Failed	Placed	Failed
Narrow Platform (NP)				
10 mm	0	0	3	0
13 mm	0	0	1	0
16 mm	1	0	2	0
Regular Platform (RP)				
10 mm	0	0	12	0
13 mm	3	0	15	0
16 mm	2	0	2	0
Wide Platform (WP)				
10 mm	1	0	9	1
13 mm	2	0	5	0
16 mm	3	0	0	0
Total	12	0	49	1

Table 1b Specification of Implant Length and Diameter for the NobelDirect 1-piece Implants

	Maxilla		Mandible	
	Placed	Failed	Placed	Failed
Narrow Platform (NP)				
10 mm	1	0	2	0
13 mm	3	0	5	0
16 mm	1	0	1	0
Regular Platform (RP)				
10 mm	1	0	18	0
13 mm	12	0	13	0
16 mm	9	0	9	1
Wide Platform (WP)				
10 mm	1	0	6	1
13 mm	0	0	5	0
16 mm	1	0	3	0
Total	29	0	62	2

months after implant placement. In addition, 21 subjects (24%) corresponding to 27 implants had attended the 2-year follow-up.

Two subjects failed to appear at the 6-month follow-up and were withdrawn from the study. One subject with 1 implant was withdrawn when the implant failed at the 1-year follow-up. All data from these subjects are included in this report.

Implant Stability

At placement, no implant failed to reach the final tightening torque of 35 to 45 Ncm. However, 1 implant achieved only questionable stability and was removed 1 month later due to instability. Another implant was due to pain removed 7 months postloading. Thus, 2 of 152 implants were removed, resulting in a survival rate after 1 year of 98.7%. Of the 27 implants that have been followed for 2 years, 1 implant was removed following excessive bone resorption, resulting in a survival rate after up to 2 years of 97.9%. Two of the subjects with failed implants, received more implants, and are followed within the study. A life table analysis is presented in Table 4. No serious, device-related adverse events were reported within the study. The reported nonserious adverse events were an abscess occurring 1 month after implant placement from subgingival resin infiltration in 1 subject; palatal gingival retraction after 6 months' follow-up around 1 of 5 implants in 1 subject; failure of the soft tissue to attach to the implant in 1 subject, detected at the 6-month follow-up; and visible metal color through the mucosa in 2 subjects, 1 at the 6-month follow-up and 1 at the 1-year follow-up.

Marginal Bone Level

The marginal bone level, ie, the position of the marginal bone as compared to the reference point at

Table 2 Implant Distribution According to Bone Quality and Quantity

	Quality				
Quantity	1	2	3	4	Total
A	4	28	12	0	44
B	1	31(2)	22	1	55
C	0	24(1)	17	2	43
D	0	4	4	2	10
E	0	0	0	0	0
Total	5	87	55	5	152

Failed implants shown in parentheses.

Table 3 Implant Distribution with Respect to Position

	Maxilla	Mandible
Central incisor		
Right	5	0
Left	3	0
Lateral incisor		
Right	2	1
Left	5	3
Canine		
Right	1	4
Left	1	5
First premolar		
Right	9	4
Left	3	8
Second premolar		
Right	2	16
Left	5	16
First molar		
Right	2	14
Left	2	24
Second molar		
Right	1	10
Left	0	6
Third molar		
Right	0	0
Left	0	0

Table 4 Life Table Analysis

	Placed/ followed implants	Failed	Withdrawn	Data missing*	CSR (%)
Placement to 3 mo	152	1	0	0	99.3
3 to 6 mo	151	0	2	1	99.3
6 mo to 1 y	148	1	0	9	98.7
1 to 2 y	138				

CSR = cumulative survival rate.
*Implants belonging to the 6 patients that had not yet attended the 1-year follow-up at the time of the study.

Table 5a Marginal Bone Levels by Follow-up Visit: Summary

	Implant placement	6 mo	1 y	2 y
No.	141	138	123	26
Mean (mm)	0.33	−0.77	−0.98	0.17
SD	1.20	1.33	1.38	1.20

Table 5b Presentation of Marginal Bone Levels by Follow-up Visit: Distribution by Level

	Implant placement		6 mo		1 y		2 y	
	n	%	n	%*	n	%	n	%
> 0	81	57	36	26	25	20	11	42
0	10	7	7	5	5	4	3	12
−0.1 to −1.0	33	23	38	28	33	27	8	31
−1.1 to −2.0	12	9	37	27	38	31	4	15
−2.1 to −3.0	4	3	12	9	15	12	0	0
> −3.0	1	1	8	6	7	6	0	0

*Because of rounding, column shows > 100%.

implant placement, was on average 0.33 mm (SD 1.20 mm, n = 141), ie, coronal to the reference point. At 6 months, the average marginal bone level was −0.77 mm (SD 1.33, n = 138), and at 1 year it was −0.98 mm (SD 1.38, n = 123), ie, apical to the reference point (Table 5a). Of the 7 implants showing a bone level > 3.0 mm apical to the reference point at the 1-year follow-up (Table 5b), 4 had a bone level between 3 and 4 mm apical to the reference point, and the remaining 3 implants had a bone level between 4 and 6 mm apical to the reference point. The average bone level for the subjects attending the 2-year follow-up was 0.17 mm (SD 1.20, n = 26) relative to the reference point (Table 5a, Figs 2 and 3). Results of the statistical analysis of various parameters on the level of the marginal bone after 1 year of follow-up are presented in Table 6. The analyses of implant level showed a more apical bone level for implants placed in the maxilla ($P = .005$), placed in other positions than in the posterior mandible ($P = .02$), having a wide diameter, being in light central occlusion ($P = .04$), and not being prepared at placement ($P = .03$). There was no significant difference in bone level between the NobelPerfect 1-piece and NobelDirect implants ($P \geq .30$). There was a positive correlation between the bone level at implant placement and the bone level after 12 months of follow-up ($r = 0.34$, $P < .001$). None of the remaining parameters were found to influence the marginal bone level after 1 year of loading. When analyzed on the subject level, the statistical differences in jaw type remained ($P = .05$) as well as the correlation between the bone levels at placement and after 12 months ($r = 0.34$, $P = .008$).

Marginal Bone Remodeling

When analyzing the influence of the various parameters on the marginal bone remodeling (ie, the change in marginal bone level) after 1 year of follow-up, it was found that implants placed using a flap showed greater bone remodeling than implants placed with a flapless approach ($P = .007$). There was a negative correlation between the bone level at placement and

Table 6 Univariate Analysis of Marginal Bone Level at 12 Months on Implant Level

Variable	Implants	Mean	SD	Difference 95% CI	Difference *P*	Correlation *r*	Correlation *P*	Individual-based *P*
Type of implant					> .30			> .30
NobelPerfect 1-piece	51	−0.99	1.4	−0.5 to 0.5				
NobelDirect	72	−0.96	1.4					
Jaw				−1.3 to −0.2	.005			.05
Maxilla	36	−1.52	1.3					
Mandible	87	−0.75	1.4					
Anterior–Posterior				−1.0 to 0.0	.07			.21
Anterior	43	−1.29	1.3					
Posterior	80	−0.81	1.4					
Position				0.1 to 1.1	.02			.11
Posterior mandible	70	−0.72	1.4					
Other position	53	−1.31	1.2					
Smoking				−0.6 to 1.9	.30			> .30
No	118	−0.95	1.4					
Yes	5	−1.61	1.7					
Indication				−0.6 to 0.4	> .30			> .30
Single	55	−1.02	1.4					
Partial	67	−0.95	1.4					
Bruxism before treatment				−0.8 to 0.6	> .30			> .30
No	106	−0.99	1.4					
Yes	17	−0.90	0.9					
Bone quality				−0.3 to 0.7	> .30			> .30
1 to 2	70	−0.91	1.5					
3 to 4	53	−1.06	1.1					
Bone quantity						−.04	> .30	> .30
A	28	−1.00	1.5					
B	44	−0.80	1.4					
C	42	−1.16	1.3					
D	9	−0.89	1.4					
Bone level at placement	122					.34	< .001	.008
Platform				0.1 to 1.3	.02			.10
NP–RP	95	−0.81	1.3					
WP	28	−1.53	1.5					
Implant length						− .04	> .30	> .30
10 mm	44	−1.09	1.4					
13 mm	50	−0.67	1.3					
16 mm	29	−1.32	1.5					
Flap design				−0.8 to 0.4	> .30*			> .30
No flap	17	−1.39	1.5					
Flap	84	−0.95	1.4					
Use of punch	22	−0.75	1.1					
Site				0.0 to 1.4	.053			.19
Healed	107	−0.88	1.3					
Extraction	16	−1.60	1.6					
Loading				0.0 to 1.0	.04			.16
Out of occlusion	63	−0.73	1.4					
Light central occlusion	60	−1.24	1.3					
Intraoral prep at placement				−1.2 to −0.1	.03			.14
No	93	−1.13	1.4					
Yes	30	−0.50	1.3					
Bone grafting				−1.0 to 0.5	> .30			> .30
No	108	−1.00	1.4					
Yes	15	−0.77	1.4					
Plaque at follow-up				−0.8 to 0.1	.17			> .30
No	60	−1.15	1.3					
Yes	63	−0.81	1.4					
Bleeding at follow-up				−0.7 to 0.5	> .30			> .30
No	96	−1.00	1.4					
Yes	27	−0.89	1.5					

*Flap versus flapless.
All implants are included in analyses.

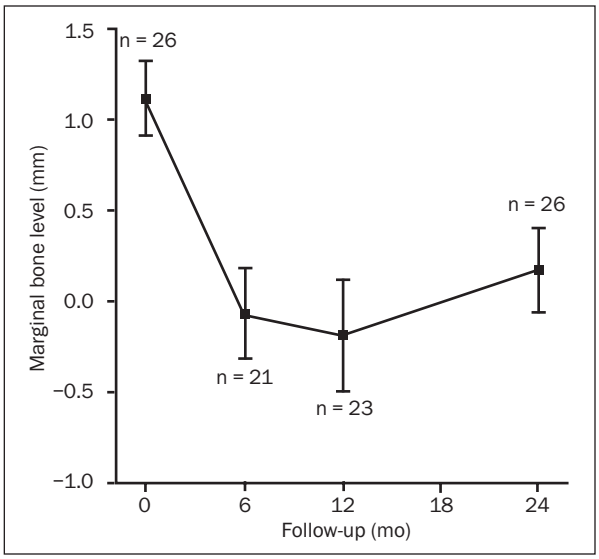

Fig 2 Marginal bone level (mean of the distal and mesial values ± SEM) for all implants with follow-up at 24 months.

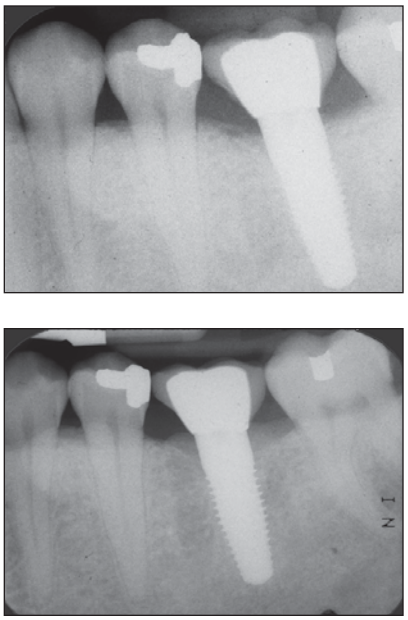

Fig 3 Radiographs from a single-tooth replacement in the mandible *(a)* 1 year and *(b)* 2 years after implant placement.

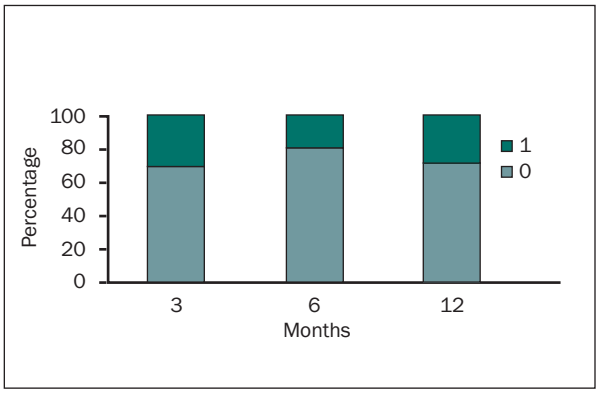

Fig 4a Presence of visible plaque during the course of the study. 0 = no visible plaque; 1 = visible plaque.

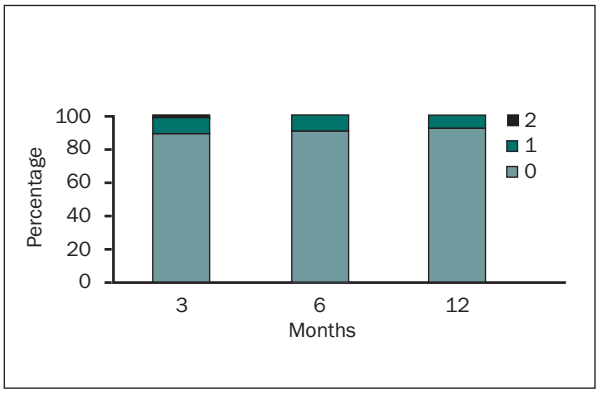

Fig 4b Evaluation of peri-implant mucosa. 0 = a normal mucosa, 1 = bleeding on superficial probing, and 2 = discoloration and spontaneous bleeding.

marginal bone loss after 1 year of follow-up ($r = –0.48$, $P < .001$). No statistically significant differences were found for any of the remaining parameters. When analyzed on subject level, the statistical difference between flap use and the flapless approach did not remain ($P = .06$); however, the correlation between the bone level at placement and the marginal bone remodeling remained ($r = –0.48$, $P < .001$).

Soft Tissue

The occurrence of visible plaque during the course of the study was between 20% and 30% (Fig 4a). The percentage of normal peri-implant mucosa was between 90% and 95% (Fig 4b). The average papilla score was 1.0 (SD 0.8, n = 152) at placement and 1.4 (SD 0.7, n = 141) at connection of the definitive prosthesis. Hyperplastic papillae (Jemt index score 4) were not recorded at any site or time point.

DISCUSSION

In this prospective, multicenter study, 2 implants were lost during the first year of function, resulting in a cumulative survival rate of 98.7% after 1 year. An additional implant was reported lost after 14 months; thus, the survival rate after up to 2 years of loading was 97.9%. This is within the normal range of reported implant survival rates from clinical studies of immediate function of dental implants.[8–10]

The 1-piece implant design evaluated in the present study combines the intraosseous threaded implant body, the transmucosal abutment, and the pillar for crown cementation in a single piece. This makes comparison between this design and traditional 2-piece implants with respect to bone level/remodeling problematic. With 2-stage, 2-piece implants, the baseline radiograph for bone level measurement was obtained at prosthesis delivery (ie, 4 to 7 months following implant placement). Changes in bone level that may have occurred during the healing period were not included in the calculation of marginal bone remodeling. In contrast, studies on immediate function, in which implant placement and loading coincide, do present bone changes from the day of implant placement. With the 2-piece implants, bone levels above the reference point on the implant were normally not registered, and a deeply placed implant did not differ in baseline value compared to an implant placed flush to the bone, in contrast to the baseline values for a 1-piece implant. Therefore, the only relevant comparison of bone levels between different implant designs is the bone level position relative to a reference point. This point should be the same relative to the anticipated bone integration part of the implant. A separate issue is the depth at which an implant should be placed relative to the bone crest.

The radiographs evaluated at the 1-year follow-up included 81% of the implants in the study, which is a normal outcome in the published literature.[11–13] Radiographs of the remaining implants were either not readable (6.5%), missing (3.5%), or not obtained (either because not enough time had passed [6.5%] or because the implants had failed or were withdrawn [2.5%]).

The average marginal bone level after 1 year of loading (–0.98 mm relative to the reference point, SD 1.38) coincides with the level of the first implant thread. This is in accordance with earlier reports on 1-piece implants[14] and reports on 2-piece implant designs with different transmucosal heights.[9,15,16] It is also in accordance with the bone level reported for 2-piece implants after 1 year of loading, where initial remodeling of the marginal bone occurs during the first year of loading, followed by stabilization around the first thread.[12,17,18]

In analyses of parameters influencing the marginal bone level after 12 months of loading, the placement of implants in the maxilla was found to result in a significantly more apical bone level. No significant difference was found on the subject level to demonstrate that implant position, platform, or loading influenced marginal bone level. This might be explained by the small sample size. No indications of a negative effect of intraoral abutment preparation at the time of implant placement were found in the present study. The positive correlation between the bone level at placement and the bone level after 12 months of loading means that shallow implant positioning resulted in a more coronal bone level after 1 year, and consequently, that deep implant positioning resulted in a more apical bone level after 1 year. This is logical, since a bone level decrease, rather than a gain, is expected for all implants. Thus, if the bone level is more coronal at placement, it will also be more coronal after 1 year compared to the implants having a more apical bone level from the start. It is important, though, to not confuse the bone level with the actual remodeling taking place between placement and the 1-year follow-up.

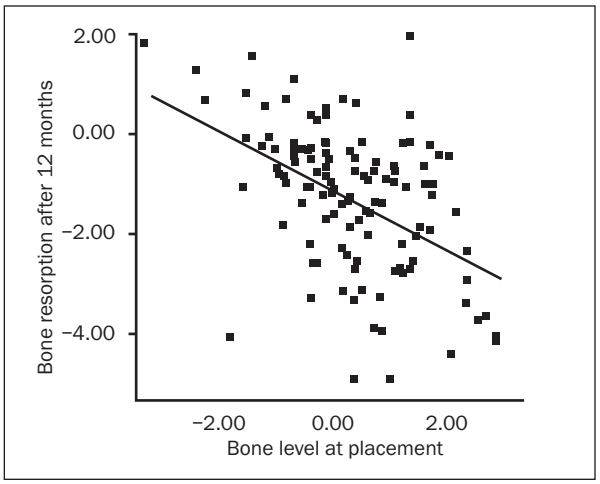

Fig 5 Scatter plot of the correlation between bone level at placement and bone remodeling 12 months after implant placement.

In the analyses of parameters influencing the marginal bone remodeling, a statistical difference was not demonstrated on the subject level between implants placed with a flapless approach in comparison to a flap technique. Once again, this may be explained by the small sample size. The negative correlation between bone level at placement and the bone remodeling between placement and 12 months of loading remained on the subject level and means that shallow implant positioning resulted in less marginal bone remodeling after 1 year of follow-up compared to deep implant positioning. Different factors need to be taken into consideration when planning the height positioning of an implant, such as the contour of the bone, the height of the soft tissue, and the space available to the opposite jaw. It is therefore not always desirable to strive for a height positioning leading to a minimum of bone remodeling. The negative correlation between bone resorption after 12 months and bone level at placement was limited (Fig 5).

Eighteen percent of the implants in the present study had a bone level > 2 mm apical to the reference point at the 1-year follow-up. All such implants remained in function and were surviving according to the definition used. Details of radiographic data, such as frequency distribution and reference point used, are usually not reported in publications on dental implants, and only a few studies have been found to which data from the present study can be compared. Glauser et al[19] reported on 2-piece implants placed in immediate function; in that sample, 18% of the implants exhibited a bone level > 2 mm apical to the reference point after 1 year of loading. A multicenter study reported by Friberg et al[20] demonstrated that 19% to 20% of the implants had > 2 mm bone loss.

The increasing number of favorable soft tissue responses at the time of definitive restoration delivery indicates a healthy soft tissue reaction with this 1-piece implant. The average papilla index of 1.0 at placement was rather low. However, the maturation of papillae at the time of definitive restoration delivery is in keeping with previous reports.[19,21] As this 1-piece implant allowed for minimal disturbance of the soft tissue during healing, it could be expected that the unperturbed soft tissue would result in maintenance of bone level position. However, this was not the case, as the bone resorbed but stabilized at the first thread.

CONCLUSION

The stable marginal bone level and soft tissue support the hypothesis that the 1-piece implant has the capacity to preserve both hard and soft tissue.

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