Soft Tissue Conditions and Marginal Bone Changes around Immediately Loaded Implants Inserted in Edentate Jaws Following Computer Guided Treatment Planning and Flapless Surgery: A ≥1-Year Clinical Follow-Up Study

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ABSTRACT

Background: Evaluation of the clinical conditions following computer guided treatment planning and flapless surgery is still limited.

Objectives: The objective was to evaluate the soft tissue conditions and marginal bone changes after 1 year of function around immediately loaded implants inserted in edentate jaws following computer guided treatment planning and flapless surgery.

Material and Methods: Twenty-nine edentate jaws (19 maxillae, 10 mandibles) treated with 165 implants using the Teeth-in-an-HourTM protocol were included. In these patients, peri-implant soft tissue conditions and radiographic marginal bone changes were evaluated after \geq 1 year of functional loading (mean: 19 months).

Results: The mean probing depth at case level was 2.6 mm (SD: 0.6). Bleeding on probing was recorded as a mean of 81.9% (SD: 23.0). Plaque index showed a wide range of 0–100%. The mean marginal bone change of measured sites evaluated on intraoral radiographs was –1.2 mm (SD: 1.4). A marginal bone loss more than 1.5 mm or 2.0 mm was observed in 42% and 27% of the measured sites, respectively. A pressure-like-ulcer was found in 9 cases. Implants with marginal bone loss of >1.5 mm were more frequently observed in cases with an ulcer than cases where no ulcer was found.

Conclusion: Although the mean marginal bone loss after function in the present study was within the range of other reports presenting mean bone loss data after immediate implant loading, our patients showed a wide range of bone loss with several sites, where the bone loss was greater than the commonly used successful level (>1.5 mm).

KEY WORDS: clinical follow-up, dental implant, guided surgery, immediate loading, marginal bone loss, soft tissue condition

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DOI 10.1111/j.1708-8208.2009.00243.x

INTRODUCTION

Since the osseointegrated implant treatment was introduced in the 1960s,¹ a significant number of studies have been conducted in order to provide patients with a safe but also more rapid treatment. The potential of the original method has led to further developments, aiming at simplifying the surgical technique and minimizing the patient's discomfort between implant insertion and prosthesis connection. Over the last decade, a number of studies have presented results comparable to the conventional two-stage surgical protocol using either early or immediate functional loading.^{2–10}

One of the newly introduced systems is the Nobel Guide™/Teeth-in-an-Hour™ concept (Nobel Biocare AB, Göteborg, Sweden). In this system, implants are inserted by the aid of a surgical template, fabricated with a rapid prototyping technique based on threedimensional (3D) virtual treatment planning (Procera® Software 3D planning; Nobel Biocare AB). The surgical template enables the surgeon to insert the implants, without raising a flap, in a preplanned position with respect to both anatomical and prosthetic considerations. A rigid prefabricated implant-supported prosthesis can, thereafter, be immediately connected to the inserted implants. Thus, the surgical and prosthetic procedure may be completed within 30-45 minutes, giving immediate function for the patient. In addition to the short surgical time needed, the flapless procedure might result in minimal postsurgical discomfort, such as pain and swelling.11,12

Although positive results have been presented in several reports using this technique,^{13–17} the reported scientific data have focused mainly on the survival/ success of the inserted implants and fixed dental prosthesis. Reports on clinical performance and follow-up are still limited. Only a few studies have evaluated the clinical condition of the supporting peri-implant tissues, including marginal bone loss.^{16–18} However, parameters, such as presence of clinical inflammation, probing depth (PD) and changes in marginal bone level also reflect the clinical performance and supporting tissue reactions during follow-up. Survival of implants and fixed dental prostheses of 31 out of 34 treated cases has been reported in a recent publication.¹⁹

The objective of the present prospective study was to evaluate the soft tissue conditions and marginal bone changes after 1 year of function around immediately loaded implants, inserted in edentate jaws according to the Nobel Guide[™]/Teeth-in-an-Hour[™] protocol (Nobel Biocare AB).

MATERIAL AND METHODS

Patients

Between September 2003 and May 2007, 34 edentate jaws (21 maxillae, 13 mandibles) were consecutively treated according to the concept of the Nobel Guide[™]/ Teeth-in-an-Hour[™] (Nobel Biocare AB). All patients were referred from their general practitioners for treatment with implant supported reconstructions. In total, 191 Brånemark System[®] MkIII TiUnite[™] RP (Regular Platform) implants (Nobel Biocare AB) were inserted with a flapless surgical procedure according to the manual for computer guided implant insertion and immediate function of edentate jaws (Nobel Guide[™]/ Teeth-in-an-Hour[™]).

The patients underwent clinical and radiographical examinations before treatment. In addition to general health requirements for conventional implant treatments, patients had to be able to open the mouth at least 50 mm (between the residual ridge and the incisal edge of the opposing anterior dentition) in order to accommodate the surgical tooling. To be included in the study, sufficient bone volume had to be present to allow for the insertion of a minimum of five fixtures in the edentate jaw.

All implants were inserted by the aid of the surgical template, which was fabricated based on 3D virtual treatment, without raising a flap. Immediately after implant placement, a prefabricated implant supported prosthesis was connected to the inserted implants. All patients were treated by one surgeon (BK) and have been followed at the Department of Dental Medicine, Division of Periodontology, Karolinska Institutet, Huddinge, Sweden.

All patients were followed up at 1 day, 1 week, 1 month, 3 months, 6 months, and 12 months after insertion of fixtures and delivery of implant prosthesis. At the 1-week examination, patients were individually instructed to start brushing with a soft toothbrush. Patients received oral hygiene instruction and training in self-performed plaque control by a dental hygienist within 2 weeks after surgery. The oral hygiene instruction included individual guidelines and training in the use of a soft toothbrush, interdental brushes, and dental floss. After 12 months, patients were routinely recalled for clinical check up once a year. Further details of the treatment procedure have been previously described.¹⁹

After a minimum of 1 year (mean: 19 months) of functional loading, all patients were recalled for evaluation of peri-implant soft tissue conditions, individual implant stability and radiographic marginal bone loss. Five out of 34 treated cases (number of cases = number of jaws) were lost to follow-up due to implants' losses (four cases) or misfit of bridge-implant (one case) during the first year, which resulted in disconnection of the suprastructure.¹⁹ Mean age of the patients at reevaluation was 71.9 years (range: 44–92 years). Three of the 29 cases included in the follow-up were smokers. The study was approved by the Ethics Committee at the Karolinska University Hospital, Huddinge, Sweden (Dnr: 3493/2005), and all patients were informed of the study protocol and signed an informed consent.

Assessment of Treatment Outcome

At the ≥1-year evaluation, clinical conditions of the periimplant soft tissues including plaque index (PI), probing depth (PD), bleeding on probing (BoP) were assessed. In addition, radiographic marginal bone changes around implants, as well as implant stability of each implant, were evaluated. In three cases (two patients), a compromised physical condition only allowed clinical examinations and radiographic evaluation without the removal of the implant supported fixed dental prosthesis. Both patients suffered from a severe chronic obstructive lung disease that had deteriorated considerably during the past year. To minimize the chair time, the follow-up examination was carried out without removing the suprastructure. Because the protocol for the clinical assessments was not followed in these patients, the clinical assessments made were therefore excluded from the database and further statistical analyses. In all other 26 cases, clinical assessments and radiographic examinations were performed after the removal of the fixed dental prosthesis. Details of the clinical and radiographic assessments amongst the patients included are presented in Table 1. A flow chart of the examination procedure is shown in Figure 1.

Plaque Registration, Probing Depth, and Clinical Inflammation

Before removal of the fixed dental prosthesis, visible plaque around the implants was registered at four sites (buccal, lingual, mesial, distal), scoring in a binominal fashion (0 = no plaque, 1 = plaque). The percentage of implant surfaces covered with plaque was calculated at case level.

Subsequently, the prosthesis and the specially designed abutments were removed. Plastic impression copings were temporarily attached to individual implants to avoid collapse of the peri-implant soft tissue. To easily measure probing depth around implants, the cylinder of the plastic impression copings were slightly modified by the manufacturer (straight and narrow), in line with the exterior wall of the implant collar (Figure 2). PD was measured from the peri-implant mucosal margin to the bottom of the peri-implant sulcus at six sites around each implant (distobuccal, midbuccal, mesiobuccal, mesiolingual, midlingual, and distolingual) using a force-controlled calibrated periodontal probe (Florida Probe®, Florida Probe Corporation, Gainesville, FL, USA) with a constant probing force of 15 g. Clinical inflammation was assessed according to Gingival Bleeding Index,²⁰ which scored the bleeding after gentle probing (0 = no bleeding, 1 = bleeding) and the percentage of bleeding sites were calculated.

Implant Stability

The stability of each implant at follow-up was measured by resonance frequency analysis (RFA) using an Osstell instrument (Integration Diagnosis AB, Sävedalen, Sweden). Following assessment of PD and BoP, the plastic impression copings were removed and an Osstell transducer was connected to the implant platform. The Implant Stability Quotient (ISQ) of each implant was registered. In 12 of the 29 cases, implant stability had been measured during the implant insertion as well and in these cases the ISQ were compared to the ISQ obtained at the \geq 1-year follow-up.

Radiographic Examination

A panoramic radiograph (Scanora[®] dental program, magnification 1.7; Soredex, Orion Corporation, Helsinki, Finland), as well as intraoral radiographs (Focus[™], Instrumentarium, Tuusula, Finland) using a long-cone paralleling technique were taken in all patients. After the radiographic examination, the prosthesis was re-connected to the implants.

Evaluation of Marginal Bone Changes

Panoramic Radiograph. The marginal bone level was assessed on the panoramic radiographs taken immediately after the implant surgery and at the \geq 1-year follow-up in all 29 cases. The peak of the most coronal thread of the implant was defined as the reference point (Thread 1, Figure 3) for the evaluation of radiographic marginal bone loss. The marginal bone height, at the mesial and distal implant surfaces, was calculated as the number of fixture threads from the reference point to the marginal bone-to-implant contact. If the marginal bone appeared at a more coronal level to the first fixture thread, the marginal bone height was recorded as "0," independent of the distance between the thread and the

TABLE 1	Details of the	e Examinati	ions of 29 Ca	ises				
		Surgery	Post-Op R	adiographs	≥1-Year Follow-Up			
Pat. No.	Position*	ISQ	Panorama	Intraoral	Panorama	Intraoral	ISQ	Clinical Examinations ⁺
1 BT^{\ddagger}	U		Х		Х		Exclue	ded due to exceptional essment protocol
2 WA	U		Х		Х	Х	Х	X
3 KM	U		Х		Х	Х	Х	Х
4 LL	U		Х		Х	Х	Х	Х
5 PE	U		Х		Х	Х	Х	Х
6 BT^{\ddagger}	L		Х		Х		Exclu	ded due to exceptional
							asso	essment protocol
7 IE	U		Х		Х	Х	Exclu	ded due to exceptional
	TT		v		v	v	v	v
δ ZG	U		A V		A V	A V	А	A V
9 AIVI	U		A V		A V	A V	v	A V
10 DI	U		A V		A V	A V	A V	A V
			A V		A V	A V	A V	A V
12 IVIV	U		A V	v	A V	A V	A V	A V
15 PA	U		A V	Λ	A V	A V	A V	A V
14 LK	L		A V		A V	A V	A V	A V
15 DU	L		A V		A V	A V	A V	A V
10 AD			A V		A V	A V	А	A V
17 ГЈ 19 DD	U	v	A V	v	A V	A V	v	A V
10 FK	U	A V	A V	A V	A V	A V	A V	A V
19 HU	U	A V	A V	A V	A V	A V	A V	A V
20 WU 21 MB	U	A V	A V	A V	A V	A V	A V	A V
21 MD	U	A V	X X	X V	A V	A V	A V	A V
22 INK 23 TK‡	U	A V	X X	X V	A V	A V	A V	A V
23 IK 24 BH	U	л V	X	X	X	л V	A X	X
24 DH 25 HM	U I	X	X	X	X	X	X	X
25 IIM	L	л V	X	A X(unclear)	X	л V	л Х	X
20 AW	L	X V	X	X(uncical)	X V	X V	X V	X
27 LII 28 NR‡	L	A V	A Y	X	X	A Y	л V	A V
20 TK	L	A V	A Y	X	A X	A Y	л V	A V
Total No	II = 10	12	л 20	13	20	л 27	л 24	л 26
10141 110.	L = 10	12	23	15	27	21	24	20

*U = upper jaw, L = lower jaw.

[†]Clinical examinations: PI, PD, and BoP.

*Patients treated both in the maxilla and mandible.

marginal bone crest (Figure 3). The number of threads was rounded to the closest 0.5. To evaluate marginal bone loss, the number of threads was calculated on the panoramic radiograph from surgery and compared to that taken at the \geq 1-year follow-up. The measurements were carried out by two calibrated readers (AK and DB).

Intraoral-Radiograph. In addition to the dental panorama, complementary intraoral radiographs were taken in 13 cases immediately after surgery and at follow-up. Only those radiographs perpendicular to the implant were included in the evaluation of marginal bone loss. Marginal bone height was measured as the distance between the reference point (Thread 1) and the



Figure 1 Flow chart detailing the examination procedures of 29 cases (number of cases in parentheses).

marginal bone crest (Figure 3). The measurements were made at the mesial and distal surfaces by two readers (AK and DB), using a magnifying lens with 0.1 mm scales (PEAK Scale Lupe x7, Tokai Sangyo, Tokyo, Japan). Calibration was performed between the two observers. When more than one bone margin was observed, the most apical margin was used for calculation. Each of the observers repeated the readings twice, allowing an interval of at least 2 weeks between the readings.

Marginal Bone Loss at Different Cut-Off Levels. To investigate the variation in bone changes during functional loading, as evaluated on intraoral radiographs, the cut-off levels of 1.0 mm, 1.5 mm, and 2.0 mm marginal bone loss were chosen. A receiver operating characteris-



Figure 2 Examination of PD around implants with modified impression copings.

tic curve was made in order to evaluate the validity of chosen cut-off values. In cases with pressure-like-ulcers, the sensitivity and specificity were higher when the cutoff levels were set to 1.5 mm or 2.0 mm. The proportion of the number of sites showing marginal bone loss above the cut-off values was compared between the maxilla and mandible and in cases with and without pressurelike-ulcers.

Statistical Analysis

All statistical analyses were conducted using STATIS-TICA 7.0 (Statsoft Inc., Tulsa, OK, USA). Data from all measured sites were transformed to individual jaw means when analyzed at case level. The Mann-Whitney *U* test was used to calculate differences at case level, but was also employed at fixture level, when data were compared between individual jaws. The Pearson chi-square test was used to detect differences in the proportion of sites, showing bone loss above the cut-off levels of 1.5 mm or 2.0 mm as evaluated on the intraoral radiographs between maxilla and mandible, and between the cases with and without the ulcer.

RESULTS

In total, 3 out of 165 implants were found to be disintegrated in two cases at the \geq 1-year follow-up and were thus removed. The abutment screw was found to be loose in 15 implants; however, no abutment screw was broken. In spite of these complications, all the 29 fixed dental prostheses were still stable and remained functional at the \geq 1-year follow-up.

In nine cases, a pressure-like-ulcer was observed when the fixed prosthesis was removed (Figure 4). This was most likely caused by the tight contact between the mucosa and the basal surface of the prosthesis. The ulcer healed uneventfully after redundant acrylic and/or metal on the prosthesis was removed.

Soft Tissue Condition

Clinical assessments of the peri-implant soft tissue (PD, BoP), as well as the presence of plaque, were made around 148 implants (maxilla: 101, mandible: 47) in 26 out of 29 cases. The results of the clinical assessments at case level are presented in Table 2.

PD was significantly deeper in the maxilla compared with the mandible, both at case (p = .02) and at implant level (p < .0001). PD more than 4 mm was noted in 19.6% of all measured sites in the maxilla and 6.4% in the mandible.



Figure 3 Reference points used in panoramic and intraoral radiograph measurements.



Figure 4 Pressure ulcers caused by tight contact of the prosthesis with the basal surface.

No difference in BoP or visible plaque around fixtures was observed between the maxilla and mandible, and the mean of both plaque index and BoP showed a wide individual range (PI: 0–100%, BoP: 16–100%).

In the cases with the pressure-like-ulcer and tight contact between the soft tissue and the basal surface of the fixed dental prosthesis, accumulation of plaque and debris was frequently observed under the prosthesis. However, no statistically significant difference was detected between the cases with and without a pressurelike-ulcer in PD and BoP.

TABLE 2 Soft Tissue Condition at ≥1-Year Follow-Up (at Case Level)											
	PI (%)			PD (mm)			BoP (%)				
Position (No. of Cases)	Mean (SD)	Min	Max	Mean (SD)	Min	Max	Mean (SD)	Min	Max		
Max + Mand (26)	45.2 (37.0)	0.0	100	2.6 (0.6)	1.4	4	81.9 (23.0)	15.8	100		
Maxilla (17)	39.4 (35.4)	0.0	100	2.8 (0.6)	1.5	3.7	79.8 (26.1)	15.8	100		
Mandible (9)	56.1 (39.6)	0.0	100	2.1 (0.5)	1.4	2.8	85.9 (16.5)	50.0	100		
<i>p</i> Value*	n.s.			<i>p</i> = .02			n.s.				

*p Values calculated with Mann-Whitney U test.

TABLE 3 Radiographic Changes of Mean Marginal Bone Levels from the Time of Surgery to ≥1-Year Follow-Up (Panoramic Radiograph)

		Maxilla	Maxilla		e	Maxilla + Mandible	
Mean Marginal Bone Changes (Threads)				Frequenc	у		
		No. of Sites	(%)	No. of Sites	(%)	No. of Sites	(%)
All measured sites							
	2	2	1.7	0	0.0	2	1.0
	1.5	0	0.0	0	0.0	0	0.0
	1	1	0.8	2	2.7	3	1.6
Bone gain (+)	0.5	0	0.0	0	0.0	0	0.0
	0	32	27.1	29	38.7	61	31.6
Bone loss (–)	0.5	0	0.0	0	0.0	0	0.0
	1	33	28.0	21	28.0	54	28.0
	1.5	3	2.5	0	0.0	3	1.6
	2	26	22.0	4	5.3	30	15.5
	2.5	1	0.8	0	0.0	1	0.5
	3	13	11.0	8	10.7	21	10.9
	3.5	0	0.0	2	2.7	2	1.0
	4	5	4.2	7	9.3	12	6.2
	4.5	0	0.0	0	0.0	0	0.0
+	≥5	2	1.7	2	2.7	4	2.1
Total		118	100.0	75	100.0	193	100.0
Mean marginal bone changes (SD)		-1.34 (1.36)	n.s.*	-1.41 (2.0)		-1.37 (1.64)	
Range		2 - (-7)		1 – (–11)		2.0 - (-11)	
At case level							
Mean marginal bone changes (SD)		-1.44(0.78)	n.s.*	-1.27 (1.33)		-1.39 (0.98)	
Range		0 - (-3.25)		0 - (-4.35)		0 - (-4.35)	

*p Values calculated with Mann-Whitney U test.

Marginal Bone Changes

Panoramic Radiograph. Because of the low resolution of the panoramic radiographs in the region around the midline, only 193 of 324 sites (162 implants) were judged as readable and were included for the evaluation of marginal bone changes after function (60%). The frequency of the radiographic marginal bone changes evaluated on the panoramic radiographs is presented in Table 3. The mean marginal bone changes of the readable sites was -1.3 fixture threads in the maxilla and -1.4 fixture threads in the mandible, which can be estimated to -0.80 mm and -0.85 mm, respectively (using a distance of 0.6 mm between fixture threads).

Intraoral Radiograph. Additional evaluation of radiographic marginal bone loss was carried out using intraoral radiographs at 136 sites (68 implants) in 13 cases (Table 4). Across all the intraoral radiographs, 11 sites (8%) were not perpendicular to the fixture threads (one case), and image was missing in four sites, and thus, they were excluded. The distribution of bone changes over the measured sites among the 12 cases is shown in Figure 5. The mean marginal bone changes of all measured sites was -1.17 mm (SD = 1.23) in the maxilla and -1.37 mm (SD = 1.76) in the mandible. Despite, there being a large deviation in marginal bone changes following the panoramic and intraoral radiographic readings, there was no difference in marginal bone changes during function between the maxilla and mandible evaluated at implant or case levels.

Evaluation at the Two Cut-Off Levels. A significantly greater number of sites showed a marginal bone loss of more than 2 mm in the mandible compared with the

TABLE 4 Radiographic Changes of Mean Marginal Bone Levels from the Time of Surgery to ≥1-Year Follow-Up (Intraoral Radiograph)

		Maxilla	Maxilla		e	Maxilla + Mandible	
				Frequency			
Mean Marginal Bone Changes (mm)		No. of Sites	(%)	No. of Sites	(%)	No. of Sites	(%)
All measured sites							
^	1.1-2.0	1	1.2	1	2.6	2	1.7
Bone gain (+)	0.1-1.0	14	16.9	13	34.2	27	22.3
	0	2	2.4	0	0.0	2	1.7
Bone loss (–)	0.1-1.0	21	25.3	3	7.9	24	19.8
	1.1-2.0	28	33.7	5	13.2	33	27.3
	2.1-3.0	10	12.0	9	23.7	19	15.7
	3.1-4.0	5	6.0	6	15.8	11	9.1
. ↓	4.1-5.0	2	2.4	1	2.6	3	2.5
Total		83	100.0	38	100	121	100
Mean marginal bone	changes (SD)	-1.17 (1.23)	n.s.*	-1.37 (1.76)		-1.23 (1.42)	
Range (mm)		1.8 - (-4.4)		1.1 - (-5.0)		1.8 - (-5.0)	
At case level							
Mean marginal bone changes (SD)		-1.26 (0.6)	n.s.*	-1.36 (1.72)		-1.29 (1.02)	
Range (mm)		-0.5 - (-2.2)		0.3 - (-3.0)		0.3 - (-3.0)	

*p Values calculated with Mann-Whitney U test.

maxilla (p = .01), although this difference between the maxilla and the mandible was not detected when the cut-off value of marginal bone loss was set at 1.5 mm (Table 5).

Of the 12 cases evaluated with intraoral radiographs, a pressure-like-ulcer was found in five cases. The proportion of measured sites with marginal bone loss of both >1.5 mm (p = .01) and >2.0 mm (p = .003) was



Cases (n=12)

Figure 5 Distribution of marginal bone changes of measured sites evaluated on intraoral radiographs in 12 cases.

TABLE 5 The Proportion of the Number of Sites with Bone Loss More Than 1.5 mm or 2.0 mm in the Maxilla and Mandible Cut-Off Level 1.5 mm Cut-Off Level 2.0 mm Bone Loss <1.5 mm Bone Loss >1.5 mm Bone Loss <2.0 mm Bone Loss >2.0 mm Total Total Maxilla 51 (61%) 32 (39%) 83 66 (80%) 17 (20%)* 83 Mandible 20 (53%) 18 (47%) 38 22 (58%) 16 (42%)* 38 p Value* p = .01n.s. Total 71 (59%) 50 (41%) 121 88 (73%) 33 (27%) 121

n = measured sites.

*p Values calculated with Pearson chi-square test.

significantly higher in the cases with a pressure-likeulcer compared to cases where no ulcer was found (p = .01) (Table 6). Regarding gender, female patients demonstrated more bone loss (mean = -1.72 mm, SD = 1.58) than male patients (mean = -0.93 mm, SD = 1.22) at implant level (p = .004).

Implant Stability

ISQ readings were obtained for 66 out of 67 implants inserted in the 12 jaws (seven maxillae and five mandibles). All these implants measured were clinically stable at the follow-up. ISQ registered during the initial surgery and at the 1-year follow-up was compared for each jaws. When comparing the obtained ISQ, it was found that the mean ISQ measured during surgery was 62.0 (SD = 7.8, range: 43-76) in the maxilla, while it was 70.6 (SD = 5.6, range: 58-82) in the mandible. Assessments, during the first year after surgery showed the mean values of both maxilla and mandible to slightly increase to 62.3 (SD = 7.0, range: 46-75) and 71.8(SD = 4.6, range: 57-79), respectively. The ISQ was significantly higher in the mandible than in the maxilla both at the initial surgery (p < .0001) and at the 1-year follow-up (p < .0001).

DISCUSSION

This study presents the conditions of peri-implant soft tissues and marginal bone changes in 29 cases, consecutively treated by means of computer-planned and flapless implant surgery with immediate loading of a prefabricated prosthesis. The overt feature of this new technique is that the implant-supported prosthesis is prefabricated and finalized based on the computer planning data before implant insertion, whereas in conventional implant treatment, the prosthesis is created according to an impression taken after implant insertion. In this technique, therefore, the accuracy of each step in the procedure will affect not only the position of the implants, but also the final outline of the fixed dental prosthesis. However, the extent of deviation that could occur at each stage has not yet been fully evaluated.21

TABLE 6 The Proportion of the Number of Sites with Bone Loss More Than 1.5 mm or 2.0 mm in Cases with and without a Pressure-Like-Ulcer

	Cut-O	off Level 1.5 mm	Cut-Off Level 2.0 mm				
	Bone Loss <1.5 mm	Bone Loss >1.5 mm	Total	Bone Loss <2.0 mm	Bone Loss >2.0 mm	Total	
No ulcer (%)	46 (69%)	21 (31%)	67	56 (84%)	11(16%)	67	
Ulcer (%)	25 (46%)	29 (54%)	54	32 (59%)	22 (41%)	54	
<i>p</i> value*	p = .01			<i>p</i> = .003			
Total	71 (59%)	50 (41%)	121	88 (73%)	33 (27%)	121	

n = measured sites.

*p Values calculated with Pearson chi-square test.

The amount of bone loss found in the present study corroborates with others presenting bone loss of immediately loaded Brånemark system[®] implants installed in edentulous jaws.^{7,22,23} In these studies, the mean bone loss was found to range between 0.6 mm to 1.3 mm, which is comparable to the bone loss during functional loading observed in the 12 cases evaluated with intraoral radiographs. The results of the current study are also comparable to the data from similar studies using flapless guided surgery and immediate loading of a prefabricated prosthesis of the CAD/CAM technique.^{15–17}

In the present study, greater bone loss was found around implants using intraoral radiographs than when the marginal bone level was evaluated on panoramic pictures, highlighting deviations between the two radiographic methods used. Although panoramic radiographs are one option for assessment of the marginal bone loss in the natural dentition,²⁴ reports regarding the applicability for monitoring marginal bone changes around dental implants are scarce. Friedland and colleagues reported that small changes in horizontal bone height may not be detectable on the panoramic radiograph due to low resolution.²⁵ In addition, the degree of magnification has been reported not to be uniform across the same panoramic survey.²⁶ Therefore, panoramic radiographs have been suggested for initial screening only using optimal conditions. In the present study, as much as 40% of all sites in the panoramic evaluations were excluded, owing to the poor image quality (eg, blurred bone margin, blunt peaks of the fixture threads or deformation of implants). The exclusion rate due to the low image quality was considerably higher than that of intraoral radiographs (8%), indicating the limited utility of panoramic radiographs for the evaluation of marginal bone levels at implants. Moreover, marginal bone changes were assessed by counting the number of fixture threads on the panoramic radiographs, while measured in distance (mm) on intraoral radiographs. On the panoramic radiographs, the bone level was always recorded as "0" if the bone margin appeared more coronal to the first thread, as the peak of the most coronal thread was selected as a reference point. Utilizing this method, restricted the detection of bone level transition, mostly bone loss, in the region that was more coronal to the first thread. Therefore, data assessed on the intraoral radiographs were used to evaluate the association between marginal bone changes and some clinical findings.

Although no significant difference between the maxilla and the mandible was detected in mean marginal bone changes, the proportion of the number of measured sites with marginal bone loss greater than 2.0 mm was statistically greater in the mandible than in the maxilla. This result contradicts with the traditional two-stage techniques, as well as techniques for early/ immediate loading.²⁷⁻²⁹ This result may be an effect of the computer guided surgical technique, and as a consequence, technical complications have also been reported to occur more frequently in the mandible than in the maxilla.¹⁹ Furthermore, when bone loss from each site was evaluated according to Albrektsson's success criteria,³⁰ as many as 41% of the measured sites were nonsuccessful, in that more than 1.5 mm of bone was lost during the first year after connection of prosthesis. Marginal bone loss of more than 2 mm was observed in as many as 27% of measured sites. This higher frequency of bone loss in this technique has also been reported by Johansson and colleagues.¹⁷ It may be reasonable to speculate that positional and angular deviations between the planning and installed implants, using the computer guided surgical protocol might lead to biological adaptation during functional loading, resulting in marginal bone loss. However, the deviation between the planning and the inserted implants using a computer guided protocol has yet to be evaluated in human studies.31,32

One notable finding during the clinical examination of the soft tissues in the present study was that a pressure-like-ulcer was observed in nine out of 29 cases (31%). The statistical analysis of marginal bone loss in the 12 cases examined with intraoral radiographs demonstrated that the percentage of the sites with marginal bone loss of >1.5 mm or >2.0 mm was greater in the cases with a pressure-like-ulcer than cases where no ulcer was found. In these cases, a reduced accessibility of oral hygiene instrumentation may have increased bone loss during the initial healing period. Local factors, such as accessibility of oral hygiene measures at implant sites, have been shown to correlate to peri-implant marginal bone loss.³³ The mean plaque score at case level was 45%, showing wide range from 0 to 100%, which may be attributed to that plaque registration was performed without removing the suprastructure. Limited visibility and accessibility only allowed for the detection of plaque presence on the prosthesis surface. Large amounts of plaque accumulation and calculus were frequently

observed on the basal surface of the suprastructure in the cases with a pressure-like-ulcer, when the suprastructure was removed. In these cases, the suprastructure was modified to obtain better accessibility for oral hygiene.

The current study demonstrated the mean BoP to be approximately 80% at case level. This high frequency of clinical inflammation around implants was consistent with several previous clinical studies. Fransson and colleagues recently reported that BoP was found around more than 90% of implants even though no progressive bone loss occurred.³⁴

Furthermore, the present study also showed a mean PD of 2.8 mm in the maxilla and 2.1 mm in the mandible at case level, which is comparable to previous studies.³⁵ Although, several reports have indicated that PD of approximately 3 mm, can be detected around successful implants, the diagnostic value of probing around implants is still not clear.³⁶ Further long-term prospective assessments of the soft tissues around implants are required to evaluate the association between PD and disease progression.

Regarding implant stability, a greater ISQ was observed in the mandibular implants than the maxillary implants, which is in accordance with previous studies.^{37,38} In the maxilla, three implants showed an ISQ value below 50 at the 1-year follow-up. Nevertheless, none of these implants showed clinical or radiographic signs of disintegration. However, if the monitoring of ISQ over time can detect failing implants requires further careful clinical observation, which has yet to be proven.³⁹

Finally, in the definition of implant success, marginal bone loss during initial healing and early functional loading, using more recently developed surgical protocols, needs to be further elucidated. Although marginal bone loss around implants has been radiographically evaluated in many studies, the "acceptable amount of bone loss" remains to be defined. The starting point for monitoring marginal bone level also varies from study to study, though most articles use the time of prosthesis connection as the starting point.⁴⁰ Since the time between implant insertion and loading is not always as long as in that of conventional treatment, it may be necessary to update the criteria according to the time of loading. Åstrand and colleagues showed that the bone loss between implant insertion and the time of loading was several times greater than between the time

of loading and 5-year follow-up, following the conventional two-stage surgical protocol.⁴¹ This implies the necessity of careful evaluation when marginal bone loss, following the one-stage surgical protocol with immediate loading, is compared to that of the two-stage procedure.

In recent years, a tendency of dental implant treatment has been focused on the reduction of treatment time and simplification of the surgical and prosthetic procedures. In these trends, a number of new implants and treatment systems are often launched without long term clinical evaluation. However, for the development of such systems, it is essential to report clinical findings, including complications objectively.

New techniques, such as the Nobel Guide[™]/Teethin-an-Hour[™], have great potentials to provide patients with an optimal treatment regarding to shortening the time needed for surgery, providing masticatory immediate function, and resulting in less post-operative discomfort. As reported in our previous publication, however, the occurrence of implant losses was higher compared to conventional protocols.¹⁹ Considering all 34 cases included in the previous and present study, the total survival rate turns out to be 90.0% at implant level and 85.3% at prosthesis level.

In the current study, the number of subjects was small and none has been followed in the long term (\geq 5 years). Although mean marginal bone loss after functional loading in the present study was within the range of other reports presenting mean bone loss data after immediate loading, our patients showed a wide range of bone loss with several sites, where the bone loss was greater (>1.5 mm) than the commonly used successful level. The outline of the fixed dental prosthesis may have influenced this finding. Therefore, further long term data are required for comprehensive evaluation and refinement of the Nobel GuideTM/Teeth-in-an-HourTM.

ACKNOWLEDGMENT

The specially designed impression copings used in the present study were kindly provided by Nobel Biocare AB, Göteborg, Sweden.

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