ORAL AND MAXILLOFACIAL IMPLANTS

Evaluation of peri-implant tissue in nonsubmerged dental implants: a multicenter retrospective study

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Objectives. The objective of this study was to evaluate the peri-implant's hard and soft tissue response associated with the 1-stage, nonsubmerged, endosseous dental implant.
Study design. A multicenter retrospective clinical evaluation was performed on 339 nonsubmerged implants placed in 108 patients at 5 clinical centers between January 2003 and December 2007.
Results. After a mean follow-up period of 30 months, the mean crestal bone resorption in 339 implants was 0.43 mm. The survival and success rates were observed to be 99.1% and 95.1%, respectively. The mean calculus, inflammatory, and plaque indices were 0.13, 0.37, and 0.73, respectively, and the mean width of buccal keratinized mucosa was observed to be 2.43 mm.
Conclusion. The short- to intermediate-term evaluation of the 1-stage, nonsubmerged, endosseous implant yields relatively high survival and success rates. **(Oral Surg Oral Med Oral Pathol Oral Radiol Endod 2009;108:189-195)**

The SSII (Osstem, Seoul, South Korea) dental implant system, a 1-stage, nonsubmerged, endosseous dental implant, represents a new implant design that has been available in South Korea since 2003. It features an internal 8° Morse tapered octagonal abutment connection, a smooth machined collar (surface roughness, 0.1-0.3 μm) without threads on the coronal part of the implant body, and a surface roughened by using resorbable blasting medium (RBM; surface roughness, 1.2-1.8 μm) with 0.8-pitch triangular threads on the body of the implant fixture. Such thread design facilities the ability for early osseointegration in weak bone quality with mastication force readily distributed, and thus can be immediately loaded. The precise, tapered, conical abutment connection eliminates the microgap often found in 2-stage implant systems.[1] It is known that the microgap allows the accumulation of food debris, bacteria, and micromovement between implant components during clinical function, thereby leading to localized inflammation and crestal bone loss.[2-5]

Because the internal octagon of SSII fixture is located in the lower area of the Morse taper and is different from other systems such as ITI, the Morse taper contact area becomes larger, thereby providing good joint stability. The collar height of the SSII fixture based on nonsubmerged placement is 1.8 mm, 2.0 mm, or 2.8 mm, and the diameter of platform can be either 4.8 mm for regular type or 6.0 mm for wide type. Fixture length is 7,0, 8.5, 10,0, 11.5, 13,0, and 15,0 mm, and as diameter, 4.1 and 4.8 mm are supplied. In principle, the SSII fixture was placed such that the boundary of the rough surface of the fixture and cervical collar was in accord with the alveolar bone crest. Depending on the thickness of the overlying soft tissue, the SSII implant connects either the cover screw or the healing abutment.

It has been reported that compared with the 2-stage submerged implant, the 1-stage nonsubmerged-type implant had a lesser marginal bone resorption, and the soft tissue condition in the vicinity was maintained

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well.[6-9] As such, the purpose of this study was to evaluate the peri-implant hard and soft tissue response associated with the SSII implants.

MATERIALS AND METHODS

The study was conducted after obtaining the approval from the Institutional Review Board of the Bundang Seoul National University Hospital (IRB No: B-0701-041-003). The patients singed an informed consent after hearing the explanation of the purpose of this study.

Between January 1, 2003, and December 31, 2007, the dental records of patients treated with SSII at Bundang Seoul National University Hospital, Chosun School of Dentistry, Chonnam School of Dentistry, Apseon Dental Hospital, and all private dental clinics were reviewed to collect data on the width and length of the implants, marginal bone loss, types of prosthetics, calculus index, gingival index, plaque index, and amount of buccal keratinized mucosa. Bone grafts performed on areas such as ridge augmentation, ridge splitting, inferior alveolar nerve repositioning, and interpositional bone grafting were excluded from the study. To standardize the data collection, criteria were established as described in the following sections.[10,11]

The width of keratinized mucosa

The width of the keratinized mucosa and the distance from the rim of gingiva of placed implant to the border of alveolar mucosa was measured.

Scores and criteria for the Calculus Index

The following scale was used to determine the Calculus Index (CI):

0: Without any plaque.
1: The mild deposition of plaque showing early calcification.
2: The deposition of plaque 0.5 mm in width on the lingual side of cervical surface.
3: The presence of the deposition of plaque 2 mm in width in the lingual side of cervical surface and the presence of deposited materials in the interdental areas.
4: Deposition more severe compared with scale 3 or deposition in the buccal side.

Scores and criteria for the Gingival Index

The following scale was used to determine the Gingival Index (GI):

0: Normal gingiva.
1: Mild inflammation–slight change in color, slight edema. No bleeding on probes.
2: Moderate inflammation–redness, edema, and glazing. Bleeding on probing.
3: Severe inflammation–marked redness and edema, ulceration. Tendency to spontaneous bleed.

Criteria for the Plaque Index

The following scale was used to determine the Plaque Index (PI):

0: No plaque in the gingival area.
1: A film of plaque adhering to the free gingiva and to the adjacent area of the tooth. The plaque may be recognized only by running a probe across the tooth surface.
2: Moderate accumulation of soft deposits within the gingival pocket, on the gingival margin, or adjacent tooth surface, which can be seen by the unaided eye.
3: Abundant soft matter within the gingival pocket or on the gingival margin and adjacent tooth surface.

Marginal bone resorption

To calculate the amount of resorption, the baseline crestal bone level measured on the peri-apical radiograph taken immediately before surgery was compared with the crestal bone level on the mesial and distal sides on the periapical radiograph taken at the last follow-up.[12] The radiographs were taken using periapical radiographs at each institution, with the conventional periapical radiograph used in 2 private offices and digital periapical radiography used (Figs. 1 and 2) in the other 3 institutions. Either short-cone paralleling, bisecting technique, or long-cone paralleling technique were used depending on the institution, whereas in other institutions, radiographs were taken using a 1-mm mesh gauge. The magnification power was adjusted using the length of the placed implants and 0.8-mm pitch length of SSII fixture. The mesial and distal sides were measured, and the mean value was calculated.

Implant survival and success

An implant was defined as "survival" if it functioned without problems. In the event of problems with the peri-implant soft tissue, the implant was defined as "survival" whenever the problems were resolved after proper treatment. An implant was defined as "success" when no mobility, tenderness, numbness, radiolucency, peri-implantitis, or progressive bone loss (<1 mm for the first year, and <0.2 mm per year from the second year) was present.[13,14]

Statistical analysis

In cases that underwent simple placement, sinus bone graft, and minor guided bone regeneration, the difference of the calculus index, gingival index, plaque index, width of keratinized mucosa, and marginal bone resorption were evaluated.

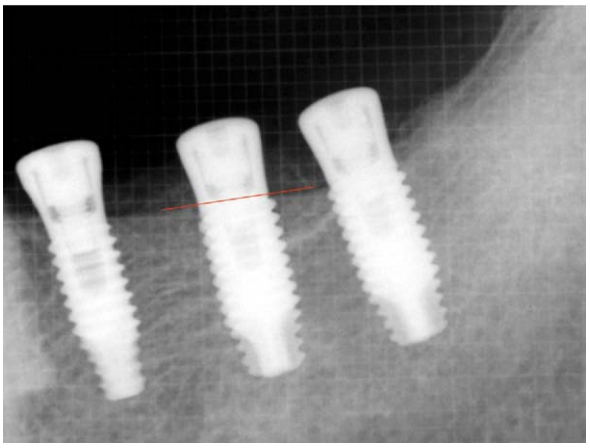

Fig. 1. Periapical radiograph taken immediately after implant placement. In the #36 area, an implant, 4.8 mm in diameter and 10 mm in length, was placed. The crestal bone level in the vicinity of implant was considered as the baseline.

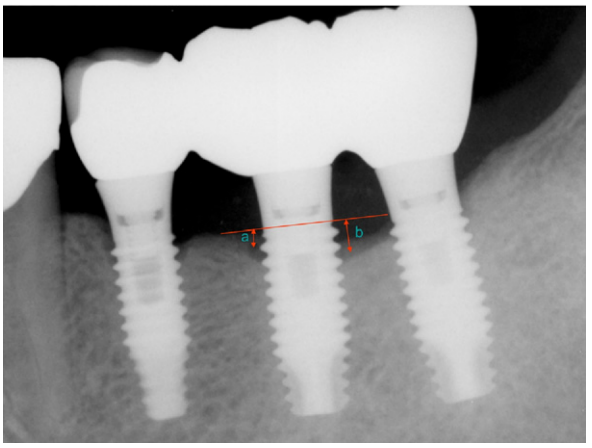

Fig. 2. Periapical radiograph taken 1 year after implant placement. Based on the baseline, the crestal bone level on the radiograph taken immediately after surgery, from mesial side (a) and distal side (b), the vertical length to the first implant-bone contact area was measured and added by referring to the magnification rate and 0.8 mm pitch, and the average was obtained. In this case, a = 0.8 mm and b = 1.2 mm, and after 1 year; the mean amount of crestal bone resorption was 1.2 mm.

Data were expressed as mean ± standard deviation descriptively and the differences of peri-implant tissue response between each group were analyzed by 1-way analysis of variance (ANOVA) and Dunkan post hoc test. SPSS version 15.0 (Chicago, IL) was used for all statistical analyses and results with a P value less than .05 were considered as being statistically significant.

RESULTS

Bone grafts that were performed in an area such as ridge augmentation, ridge splitting, inferior nerve repositioning, and interpositional bone grafting were excluded from the study.

There were 339 implants placed in 108 patients at 5 institutions. The age of the patients ranged from 25 to 76 years, with an average age of 52.8 years. There were 50 females and 58 males in the study. The follow-up period after prosthodontic loading ranged from 19 to 40 months (average, 30 months). In this study, 201 mandibular implants and 138 maxillary implants were evaluated. The mandibular molar implants were most prevalent (127), followed by maxillary molar (91), mandibular premolar (45), maxillary premolar (40), mandibular incisor (29), and maxillary incisor (7) implants (Table I). The most common lengths of the placed implants were 11.5 and 13.0 mm, which were used in 266 cases. The implant diameter was 4.1 mm in 138 cases and 4.8 mm in 201 (Table II).

In addition, 84 implants required simultaneous maxillary sinus bone grafting, 80 implants involved minor guided bone regeneration, 22 implants involved sinus bone graft and minor guided bony regeneration, and 153 implants were placed without special treatment (Table III).

Table I. Number of implants by site

	Anterior	*Premolar*	*Molar*	*Total*
Maxilla	7	40	91	138
Mandible	29	45	127	201
Total	36	85	218	339

The time interval from implant placement to the first loading of the maxilla and mandible was from 0 month (immediate loading) to 21 months (average of 8.1 months) and from 0 month to 21 months (average of 5.8 months), respectively. The major prosthesis type was a fixed partial prosthesis (64.6%), followed by a single prosthesis (21.9%). All of the observed failures involved the use of fixed partial prostheses. Additionally, the smallest marginal bone loss was observed with the use of single prostheses (Table IV).

As shown in Tables V and VI, the marginal bone loss ranged from 0 to 8 mm (average, 0.43 mm). Fifteen implants showed bone resorption exceeding 1 mm within 1 year after prosthetic delivery. The average CI, GI, and PI measured in 314 implants were 0.13, 0.37, and 0.73, respectively, and in most cases, the vicinity of implant showed the level 0 or 1 value (Tables VII, VIII and IX). In 230 implants, the keratinized mucosa width in the buccal side of the implant could be measured and an average of 2.43 mm (0 ~ 8 mm) in width was observed.

As shown in Table X, the follow-up period ranged from 19 to 40 months (average, 30 months) with a survival rate

Table II. Number of implants by size

Implant size, mm	*No. implants*
Diameter	
4.1	138
4.8	201
Length	
8.5	8
10	43
11.5	133
13	133
15	22

Table III. Types of surgery

Types of surgery	*No.*
Sinus bone graft	84
Guided bone regeneration	80
Sinus bone graft and guided bone regeneration	22
Simple implant placement	153

Table IV. Distribution of implants by type of prosthesis supported

Restoration	*No. implants*	*Marginal bone resorption, mm*	*No. failures*
Single	73	0.27	0
Fixed partial	215	0.46	3
Fixed complete	21	0.62	0
Overdenture	24	0.40	0
Total	333*		3

*Six prosthesis types were not specified.

Table V. Crestal bone resorption

Bone resorption	*No.*
None	198
0.1-0.5 mm	10
0.6-1 mm	81
1.1-2.0 mm	7
>2.0 mm	8
Total	304*

*Not specified for 35 implants.

of 99.1% (339 implants). Of the successful implants, marginal bone loss of less than 1 mm in the first year after loading was observed for 304 implants (95.1% success rate). Three implants were removed from 2 patients during the follow-up period (Table XI). Between the cases with simply placed nonsubmerged implants and the cases accompanied with sinus bone grafts and minor GBR, the CI, GI, PI, width of buccal keratinized mucosa, and marginal bone resorption, and so forth were not statistically significantly different (Table XII).

DISCUSSION

Because of the external hexagonal structure of the Branemark-type implants, the alveolar bone was reported to be resorbed up to the first thread of the screw within 1 year after placement. This partial resorption of alveolar bone is unavoidable because of the formation of biological width. With 2-stage implants, the bone loss was reported to range from 0.2 to 1.3 mm after the second surgery, suggesting that the initial bone resorption was attributed to surgical trauma.[15] Less bone resorption occurs with 1-stage ITI series implants because the formation of the gingiva by biological width occurs in the area above the alveolar bone. Buser et al.[16] reported that the loss of alveolar bone with a 1-stage implant was similar or slightly less than that with a 2-stage implant. In comparison, bone resorption was less for both 1- and 2-stage placements using a system with a microthread at the upper end of the implant fixture.[17] Marginal bone resorption of approximately 0.4 mm in the patients was reported at 1 year after implanting Astra Tech ST implants (Astra Tech AB, Mölndal, Sweden) in the maxillary anterior tooth area using the 1-stage method, followed by placement of permanent prostheses at 7 to 8 weeks after implantation.[18]

In this study, the resorption of alveolar bone was measured for 339 implants, with 198 implants showing no resorption and 15 implants showing resorption exceeding 1 mm. The resorption averaged 0.43 mm, resulting in relatively stable implants. The alveolar bone resorption according to patterns of upper prosthesis was 0.27 mm in the single-implant prostheses, 0.46 mm in partial fixed prostheses, and approximately 0.62 mm in fixed upper and lower prostheses and 0.4 mm in overdenture cases.

Using radiographs, Peñarrocha et al.[19] measured the marginal bone loss with 108 ITI implants at 1 year after prosthetic loading. Bone loss averaged 1.36 mm on panoramic radiographs, 0.76 mm on periapical radiographs, and 0.95 mm on digital radiographs. In a 3-year prospective study with an ITI implant, Behneke et al.[8] found 0.8 mm of bone resorption during the period from implant placement to prosthetic restoration, with 0.1 mm of stable bone resorption annually thereafter. Similarly, in a 5-year prospective study with an ITI implant, Hellem et al.[20] observed 0.1-mm bone resorption in the first year after implant placement and 0.1 mm of very stable bone resorption in tests performed between 1 and 5 years.

In this multicenter retrospective study, both conventional periapical radiography and digital radiography were used. In comparison with the observation period in other studies, our observation period was short and the possibility of further resorption cannot be ruled out. Nonetheless, the upper prostheses tended to be very stable at 1 year after placement, suggesting that major problems are unlikely to occur in the long term. Because this study was conducted as a multicenter retro-

Table VI. Summary of the cases with crestal bone resorption exceeding 1 mm

Site	*MBR, mm*	*Age*	*Sex*	*CI*	*GI*	*PI*	*BKM, mm*	*Final prosth*	*Opposing tooth*	*Operation*
46	1.2	63	M	0	0	0	NA	Single	Crown	
47	1.2	63	M	0	0	0	NA	Single	Crown	
36	1.8	43	M	0	0	1	NA	FP	Natural tooth	
43	2.0	61	F	NA	NA	NA	NA	OD	Edentulous	
14	2.0	63	M	0	0	1	3	FP	Natural tooth	Sinus grafting
42	2.0	50	M	1	0	1	3	FP	Prosthesis	
13	2.0	60	M	0	1	0	1	FP	Prosthesis	
16	2.2	51	M	0	0	1	NA	Single	Natural tooth	Sinus grafting
37	2.7	51	M	0	0	1	NA	Single	Natural tooth	
36	3.0	50	F	0	0	1	2	FP	Natural tooth	Sinus grafting
16	3.0	63	M	0	2	0	1	FP	Prosthesis	
47	5.0	42	M	0	0	2	2	FP	Natural tooth	GBR
17	5.0	63	M	0	0	1	2	FP	Prosthesis	sinus grafting
27	5.0	63	M	0	0	1	2	FP	Prosthesis	sinus grafting
45	8.0	42	M	0	1	2	1	FP	Natural tooth	GBR

MBR, marginal bone resorption; *CI,* calculus index; *GI,* gingival index; *BKM,* buccal keratinized mucosa; *Prosth*, prosthetics; *OD,* overdenture; *FP,* fixed partial prosthesis; *GBR,* guided bone regeneration; *NA,* not assessed.

Table VII. Calculus index

Level	*No. implants*	*%*
0	275	87.6
1	36	11.5
2	3	0.9
Total	314*	100

*25 were not specified.

Table VIII. Gingival index

Level	*No. implants*	*%*
0	220	70.1
1	75	23.9
2	15	4.7
3	4	1.3
Total	314*	100

*25 were not specified.

Table IX. Plaque index

Level	*No. implants*	*%*
0	106	33.8
1	185	58.9
2	23	7.3
Total	314*	100

*25 were not specified.

Table X. Implant failure and survival by year

Year	*No. implants at start of year*	*No. implants survival at follow-up*	*Failures*	*Survival, %*
1	339	336	3	99.1
2	336	336	0	100
3	336	336	0	100

Table XI. Distribution of failed implants

Site	*Age/ Gender*	*Implant diameter/ length, mm*	*Possible causes*	*Type of surgery*
26	66/F	4.8/11.5	Psychological	Simple
27	66/F	4.8/11.5	Psychological	Simple
46	42/M	4.1/13	Osteomyelitis, Wound dehiscence	GBR

F, female; *M,* male; *GBR,* guided bone regeneration.

spective study form, it was impossible to standardize the method for performing radiographs. However, clear radiograph image of the implant fixture thread was observed and the magnification rate was adjusted and the marginal bone resorption of mesiodistal side was measured.[12] Through digital radiography subtraction technique, the method to photograph at the ratio of 1:1 using special equipment was introduced, allowing the measurement of accurate mesiodistal bone resorption rate. However, this technique is limited, in that bone resorption at the buccal and lingual sides could not be measured. In other articles, marginal bone resorption rate was measured by adjusting the magnification rate of periapical radiography or orthopantomography. Peñarrocha et al.[19] and Watzak et al.[21] reported that conventional periapical films and digital radiographs were slightly more accurate than the measurement methods using orthopantomography.

Oral hygiene management is important for long-term implant survival. In addition, the presence of nonmovable mucosa in the vicinity of the implants is reported to be favorable for survival. After placement of an

Table XII. Differences of peri-implant tissue response according to sinus bone graft and minor guided bony regeneration

	Mean ± SD			
	Simple	*Sinus graft*	*GBR*	*Significance*
CI	0.162 ± 0.410	0.092 ± 0.291	0.0625 ± 0.244	.099
GI	0.314 ± 0.577	0.408 ± 0.570	0.438 ± 0.814	.297
PI	0.691 ± 0.584	0.776 ± 0.479	0.797 ± 0.717	.348
BKM, mm	2.402 ± 1.374	2.525 ± 1.260	2.40 ± 1.323	.829
MBR, mm	0.370 ± 0.566	0.537 ± 0.970	0.467 ± 1.306	.322

CI, calculus index; *GI,* gingival index; *PI,* plaque index; *BKM,* width of buccal keratinized mucosa; *MBR,* marginal bone resorption.

upper prosthesis, the presence of dental plaque, calculus deposition, and ongoing inflammation was suggested to increase the risk of progression to implantitis.[22] Therefore, calculus, inflammation, dental plaque indices of the 318 implants, and the amount of keratinized mucosa on the buccal side of 230 implants were measured in this study. The average calculus, gingival, and plaque indices were observed to be 0.13, 0.37, and 0.73, respectively. The average width of the keratinized mucosa to the buccal side of the implant in 230 implants was 2.4 mm. Therefore, the soft tissues near the SSII implant system were maintained in good condition. To evaluate soft tissue condition in the vicinity of implants, a variety of clinical parameters such as probing depths, tissue color, texture, gingival recession, and percent bleeding on probing are required. However, in an effort to overcome problems associated with multicenter retrospective studies, only plaque, calculus, gingival inflammatory indices, and buccal width of keratinized mucosa were evaluated to minimize measurement errors. It has also been suggested in the literature that the probing depth around implants provided no significant information and errors may be severely dependent on the instruments used, probing force, and dentists.[23] As such, probing depth was excluded from this study.

In a 5-year prospective study, Hellem et al.[20] used the deposition of calculus, bleeding on probing, and presence or absence of attached peri-implant mucosa to evaluate the soft tissues near ITI implants. The rate of calculus or plaque deposition was reported to be 26.5% after 3 years and 3.3% after 5 years. After 3 years, 1% of the cases lacked keratinized gingiva, and this decreased to 0.3% after 5 years. Bleeding on probing was seen in 19.6% of cases after 3 years and in 13.1% after 5 years. In a study on the placement of an external hex butt joint implant (Osseotite and TG Osseotite) or a tapered Morse nonsubmerged implant (3I Implant Innovations, Riverside, CA, USA), the PI was reported to average 0.742 ± 0.572 near the submerged implants and 0.855 ± 0.183 near the nonsubmerged implants.[24]

Romeo et al.[25] reported the long-term survival and success rates of ITI implants based on a 7-year prospective study. In that study, 759 implants were placed in 250 patients, with a mean observation period of 3.85 years. The cumulative survival rates were reported to be 95.6% for single-tooth prostheses, 94.4% for cantilever fixed prostheses, 96.1% for fixed prostheses, 100% for edentulous complete fixed prostheses, 90.6% for prostheses connecting a natural tooth and the implant, and 95.7% for overdenture prostheses. The success and survival rates were similar between the maxilla and mandible, and the implant size did not influence the survival rate. Based on a 3-year prospective study of ITI implants, Behneke et al.[8] reported cumulative implant survival and success rates of 98.1% and 97.1%, respectively. In a 5-year prospective study, Hellem et al.[20] reported a 95.7% survival rate and a 91.4% success rate for ITI implants.

With an average follow-up period of 30 months after prosthetic delivery in this study, the survival and success rates were observed to be 99.1% and 95.1%, respectively.

Three failed implants in 2 patients were removed. The implant placed in the mandibular first molar area of a 42-year-old male patient failed as a result of postoperative infection. The implants placed in the maxillary first and second molar area of a 66-year-old female patient were removed at the request of the patient despite successful prosthetic treatment because of her foreign body sensation to the implants.

Given that this study was retrospective and involved several variables, it was not reasonable to compare data from this study with those of prospective studies. In this study, the loading time after implant placement in the maxilla and mandible averaged 7.5 months and 5.8 months, respectively. However, in several cases where initial osseointegration was excellent and surgical techniques such as bone graft were not accompanied after implant placement, immediate loading was performed. Sinus bone grafts were performed because of the insufficient bone quality or the insufficient osseointegration of

implants. Prosthesis treatments were performed after a sufficient healing period.

The long-term prognosis of implants and the resorption of alveolar bone may differ between Koreans and other nationalities because of differences in food preferences. Koreans favor kimchi, fresh bacon, bone, and other hard, tough foods, which result in dynamic overloading of implants. Therefore, this study is significant from the perspective that the study evaluated the prognosis of the 1-stage implant in Koreans who have strong masticatory force. However, problems in this study may be attributed to the participation of multiple centers, thereby resulting in the simplification of measuring parameters for the soft tissue and the lack of the standardized measurement method that could measure marginal bone resorption accurately. In addition, the mean follow-up observation in this study was short, and thus care was taken when drawing conclusions on prosthetic complications as well as long-term efficacy.

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