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Retrospective Study of Implantium® Dental Implants: Clinical and Radiographic Results of 22 Months

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Over the last years, growing attention has been paid to the several domestic implant systems. This study presents results of a clinical trial of Implantium® implants followed up to 22 months.

Two hundred fifty-two Implantium® implants were investigated which were placed in 119 patients between June 2003 and November 2004. The average follow-up period from implant placement was 10.9 months (SD 4.9) and mean loading period was 7.9 months (SD 4.3). Survival rate of implants was evaluated. For the evaluation of marginal bone changes, only the implants in function and more than 12 months of follow-up period from installation were considered. Crestal bone loss of 118 implants was analyzed using linear radiographic measurements.

After the first surgical stage, there was no failures of implants. No implant was lost after prosthetic loading time. The crestal bone level after fixture installation and after 1 year was 0.16 ± 0.30 mm and 0.58 ± 0.64 mm, respectively. The marginal bone loss during first one year was 0.44 ± 0.55 mm.

The results obtained in this short-term retrospective study population revealed an excellent survival rate for Implantium® implants

Key words: endosseous dental implants, Implantium®, retrospective analysis

(영) Introduction

Long-term success rate for dental implants in restoring partially edentulous jaw and fully edentulous jaw has been well documented by various studies, and dental implants are now becoming a universal treatment of choice.^{1,2,3,4,5,6} As dental implant treatments widely spread since 1980s, there have been improvements in both prosthetic and surgical aspects of implant therapy such as improved initial fixation for implants at first stage surgery, earlier/immediate loading, simplified surgery techniques, various surface treatment methods, and improved prosthetic component fittings and materials. Recently, within Korea, market share of Korean-made implants have been increasing with rapid expansion of the implant market in Korea. In addition to marketing efforts, Korean implant manufacturers are increasingly playing leading roles in expanding the implant market through developing various systems and offering continuing education to practitioners. While Korean made implants, compared to European or North American made implants, are more economical, their clinical efficacy is being demonstrated through short and middle-term findings.^{7,8,9}

The design of Implantium®(Dentium, Korea), marketed since the mid-2002 is said to have following merits: initial intraosseous fixation is easy to achieve; early load is possible; [marginal bone](#) resorption is minimized; [abutment](#) connection method utilizes proven internal conical seal type; and prosthetic components are simple to use. However, since its clinical results have not yet been published, it is deemed that an objective study is necessary. Accordingly, this study is intended to examine the stability and efficacy of Implantium implants through this short-term progress observation, targeting on the patients who received implant therapy at Dental Surgery of Seoul National University Bundang Hospital since 2003.

(영) II. Study subject and methods

1. Study subject

This study was conducted on the 252 Implantium® implants placed and restored in 121 partially edentulous and fully edentulous patients who came to Dental Surgery, Seoul National University Bundang Hospital between June 2003 to Nov. 2004. Of those 121 patients, 119 patients whose progress was observable and whose clinical records and radiographs before and after having implant therapy were included in this study. The age of the patients ranged from 17 to 81 years (Table 1), and the inclusion criteria were as follows:

- Medically healthy patients, or medically compromised patients whose medical condition was under control.
- Moderate bruxism patients, providing occlusal splints after completion of implant restoration.
- Periodontally compromised patients, only after appropriate periodontal therapy and demonstrated stability of periodontal condition and improved/acceptable oral hygiene.

Patients with inability to stop heavy smoking and those who have low cooperation and comprehension level for proposed treatments were excluded from the study.

Table 1. Distribution of patients according to sex and age

Age	Males	Females	Total	%
17-29	5	7	12	10
30-49	24	21	45	38
50-69	27	30	57	48

69-81	0	5	5	4
Total	56	64	119	100

(영) 2. Study methods

Surgery

With regard to an implant placement region, the length of available bone and quality were measured on digital panoramic radiographs. Implant placement surgeries were performed by 1 oral surgeon and 3 prosthodontists.

The total number of the implants surgically placed in 119 patients was 252. Length, diameter and intra-arch location distribution of implanted implants are shown on Table 2 and 3. The condition around implantation region included: a region having type IV bone by LZ classification¹⁰; a region requiring Guided Bone Regeneration technique due to lack of horizontal or vertical bone volume; a case in which immediate implantation was needed after removal of another implant whose osseointegration had failed; as well as cases where the bone amount and quality were relatively good.

As to the second surgery, in cases where Guided Bone Regeneration technique was not conducted and initial stability was good, early load was applied in case of lower jaw in about 6 weeks after implantation and in case of upper jaw 2-3 months, using healing abutments.

In cases where initial stability was insufficient, bone quality was poor, or GBR technique was performed, the second surgery timing was determined according to the bone quality of implantation region, amount of bone graft and the type of graft materials.

Table 2. Distribution of implants according to position

Position	No. of implants	%
Upper anterior	14	6

	premolar	23	9
	molar	51	20
Lower	anterior	19	8
	premolar	25	10
	molar	118	47
	Total	252	100

Table 3. Distribution of implants according to length and diameter

Diameter (mm)	Length (mm)				Total
	8	10	12	14	
3.4	0	1	2	10	13(5%)
3.8	6	19	42	11	78(31%)
4.3	4	39	62	12	117(46%)
4.8	4	12	22	6	44(17%)
Total	14(6%)	71(28%)	128(51%)	39(15%)	252(100%)

Prosthesis operation

Restoration of implants were conducted by the 3 prosthodontists who performed implant placement surgeries 2–3 weeks after the secondary surgery. The restorations included single tooth restorations(30%), fixed partial denture or fixed complete denture prosthesis(66%), complete full overdenture(2%) and fixed partial denture supported by natural teeth and an implant (2%) (Fig. 1).

The overdenture was ball attachment type which applied 2 implants mesial to the mental foramen of lower jaw in 3 cases. Fixed bridge supported by natural teeth and an implant was applied to 5 cases and permanently cemented as conventional 3 unit bridge type in which the natural teeth abutment's periodontium was healthy and without any mobility.

Except for the case where anterior teeth were missing or a large number of teeth missing, provisional restorations were not provided. Progressive loading process through provisional restoration was omitted and final restorations were fabricated and placed after usual impression takings. In case of a patient having severely poor bone quality, the author tried to obtain an effect of applying progressive loading through educating and encouraging the patient to gradually increase masticatory function after the implant restoration placement. All of the patients came to the hospital at the intervals of 1 week, 1 month, and 3 months after completion of prosthetic treatment for observations and periodontal maintenance program,

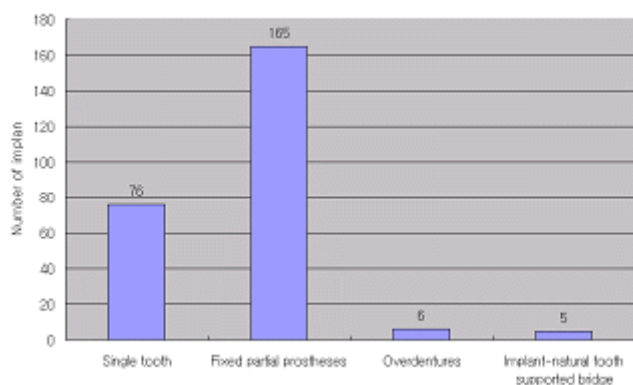


Fig 1. Distribution of implants according to type of prosthetic restoration

Clinical and radiographic evaluation

Clinical inspection and periapical radiographic inspection were conducted at implant placement surgeries, at installing of healing abutments, delivering of prosthesis, and at follow up/maintenance visits

of 1 month, 3 months, 6 months, 9 months and 12 months intervals. When patients presented to the hospital, authors conducted clinical and radiographic inspections, prosthesis and occlusal evaluations, oral hygiene evaluation and instruction, and, if necessary, supportive periodontal therapy.

Regarding the basis for implant survival, criteria set forth by Albrektsson, etc¹¹ was used to determine implant failures:

1. Upon clinical examination, whether mobility of each implant can be detected.
2. Upon radiographic examination, radiolucency around implants is observable.
3. In case where there appears symptoms such as pain, edema, infection, paresthesia, and penetration of mandibular canal.

The exact measurement of each implant mobility is possible only in case of single implant, and impossible unless the prosthesis is removed when an implant is connected with fixed prosthesis. Accordingly, mobility of all implants were not measured using objective diagnosis tools, but was determined in general consideration of comfort level and convenience for patients, and whether or not there is any pain or clinical and radiographic finding.

Measurement of marginal bone loss around implants were conducted on 118 implants when they had been in place for at least 12 months. In case of periapical radiographs, with the junction between machined surface of implant neck and SLA surface as the reference point, radiographic distance to the osseous level was linearly measured(Fig. 2). Actual measurements were calculated by comparing known values of screw peak. [Mesiodistal marginal bone level](#) of each implant was also measured and the average of measurements of 2 persons was obtained.



Fig 2. Reference point of implant

(영) III Results

1. Survival rate of an implant

The observation period of the implanted 252 implants ranged 4 months to 22 months, and the average observation period was 10.9 months(SD4.9). No implant among the 252 implants failed during this time period. The survival rate of the implants was 100%, and all implants proceeded to restorative phase (Table 4). There were 2 implants, one in each patient, which were implanted for restoration of lower second molar and were considered to be osseointegrated but which were not used due to improper implantation location or was again buried and excluded from subject of evaluation(Fig 3).

The observation period of 250 implants whose prosthesis treatment was possible was 0 ~ 18 months and an average time period was 7.9 months(SD 4.3 months), and no implant failed during the observation period. Also, there was no screw loosening of the super-structure for overdentures, nor was there fracture of parts in any of the partially edentulous or completely edentulous cases. Soft tissue around one implant showed signs of periodontitis during observation period. The thickness of gingival tissue above the fixture level was about 5mm in that case, resulting in deep gingival sulcus depth and the amount of bone loss was 0.95mm. Soft tissues around implants for rest of the cases remained healthy.

Table 4. Life table analysis of implants

Interval	No. of implants at start of interval	Drop-out		Implants under risk	Failed during interval	survival rate within interval(%)	cumulative survival rate(%)
		during interval					
		No. of implant	No. of patients				
placement to loading	252	0	0	252	0	100	100
loading to 6months	163	2	2	163	0	100	100
6months to 1y	67	0	0	67	0	100	100
1y to 18months	20	0	0	20	0	100	100

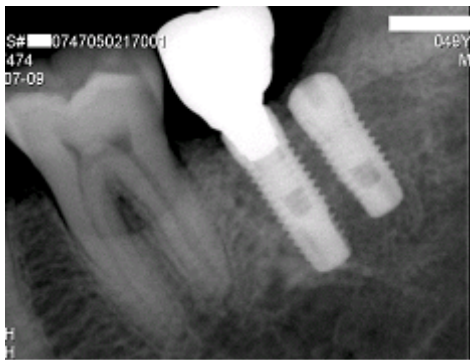


Fig 3. Distal implant was buried due to bucco-lingual malposition

2. Radiographic results

The authors measured the bone loss amounts of mesiodistal marginal bone for 118 implants in which case 1 year had elapsed after implantation(Fig 3, Table 5 and 6). Marginal bone loss immediately after implantation was 0.16mm(SD 0.30), and marginal bone loss around the implants in which case 1 year had elapsed after implantation was 0.58mm(SD 0.64). Therefore, the average marginal bone loss amount for the first year was 0.44mm(SD 0.55).

Marginal bone response for 63 implants (53%) was excellent, as there was no bone loss at all, or the bone loss stopped at the first microthread. However, during the first year after implantation, more than 1.5mm¹² of marginal bone loss occurred in 7 implants

among 6 patients. Those 7 implants are composed of 1 implant whose cover screw was exposed in the early stage due to load by temporary denture, which was eventually used for bridge support having distal extension; for 5 other implants, the flap mucosa became open in the early stage of healing after the surgery utilizing guided bone regeneration technique; and 1 implant in which case the cause of marginal bone loss was difficult to hypothesize.

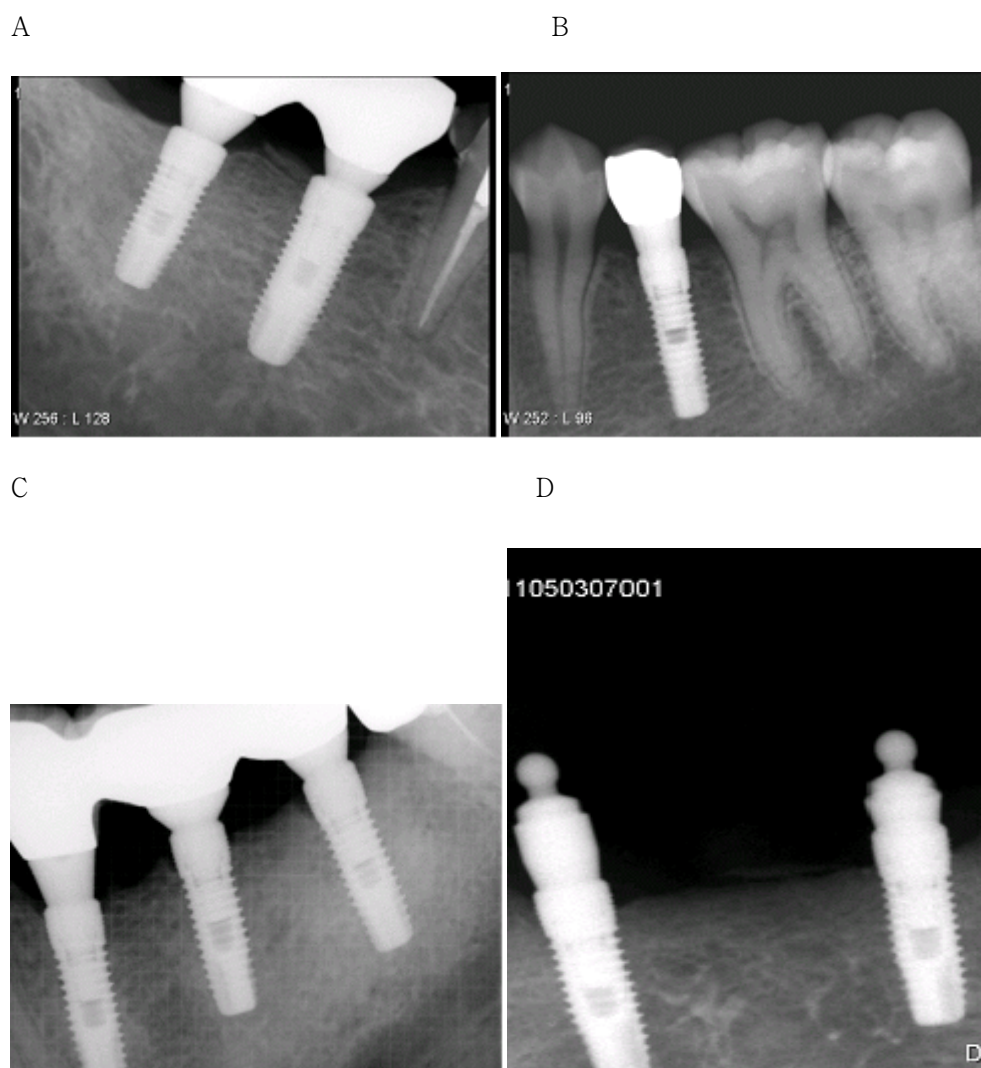


Fig 4. Crestal bone response in several cases after 1 year of loading. A, very favorable response. B, slight bone loss to the first microthread. C, vertical and horizontal bony loss. D, horizontal bony loss.

Table 5. Comparison of Marginal Bone Level After 1year

	After insertion(A)		After 1year (B)		Bone loss(A-B)	
	Mesial	Distal	Mesial	Distal	Mesial	Distal
Bone level (mm)	0.11 (SD0.27)	0.20 (SD0.32)	0.51 (SD 0.63)	0.66 (SD 0.66)	0.41 (SD 0.56)	0.46 (SD0.55)
Total	0.16(SD 0.30)		0.58(SD 0.64)		0.44(SD0.55)	

Table 6. Marginal Bone Loss(A-B) After 1 year

Bone loss(mm)	0~0.3	0.3~ 1.5			1.5~3.0
		0.3~0.6	0.6~1.0	1.0~1.5	
Number of Implant (Total 118)	63(53%)	28(24%)	13(11%)	7(6%)	7(6%)
		48(41%)			

(영) IV. Discussion

In case of Implantium® implant, its fixture surface was treated by SLA(sandblasting large grit acid etching) method, and micro thread was designed to be located in the upper part of root form fixture, so that it will be helpful for the initial stability of the fixture and discourage osteoclastic activity. It also utilizes internal conical seal for connection

method with abutments. Because there was objective report on this implant system up to now, the authors tried to find the clinical efficacy by investigating the survival rate and marginal bone response to implants by collecting data from patients who were treated at the Dental Surgery, Seoul National University Bundang Hospital between June 2003 to Nov. 2004. .

The definition of the basis of success, failure and survival of an implant is various or vague in literature¹³. Even according to recent agreement on glossaries¹⁴, implant success or survival seem to be poorly defined. In cases where progress observation is impossible in the middle term, or an implant is buried or lost, or there occurs early failure, and the method of determining such case outcome is diverse. But in this study, 2 patients, for whom progress observation was impossible in the middle term, was excluded; and 2 implants, not used for prosthesis treatment due to poor positioning was considered as survival.

In this study based on short-term clinical results, Implantium® implant showed encouraging survival rate. Regardless of various bone quality and bone quantity, there was no early failure in osseointegration of Implantium® fixture. To the extent that this study observed, prosthetic loading of all the implants was possible, and after applying load, there was no failure during observation period. It was found as stated in Report¹⁵ which examined many studies on implant survival rate that failure in osseointegration before applying load accounted for higher rate, and that most failures after prosthesis insertion occurred within 1 year. Accordingly, in spite of limitation of a short-term clinical study, this result is considered clinically significant in that there was no early failure. Also, there was no mechanical failure such as screw loosening or fracture, or complication.

This study did not record nor compare peri-implant parameters such as Plaque Index, Bleeding Index, Probing Depth, and Probing Attachment Level, etc. Since when examining peri-implant where a healthy soft tissue firmly formed defense layer around abutments, the measurements were not always exact and may give pain and an iatrogenic wound to a patient, and because the emergency profile of abutment of this system inclined from alveolar ridge line, probing was easy or in most cases its value was not exact, thus there was limitation. Therefore, in case a soft

tissue around an implant is clinically firm and healthy, and the level of marginal bone is steady, the authors essentially did not probe, but only in cases the change in the level of marginal was found in radiographic finding, a symptom of periodontitis appeared and there was no attached gingiva, probed to find whether or not bleeding occurred and measured the depth of gingival sulcus. In this observation, in clinical implant peri-implantitis, bleeding was found with some bone loss at the time of probing in one case, but inflammation of a soft tissue was healed after periodontal therapy.

Long-term measurement of each implant mobility can be conducted only when it has screw fixation type for each prosthesis. In the great number of implants which is connected to cemented type prosthesis, or the implant which is connected to natural teeth, the mobility of each implant can not be measured. In this study, almost all the implant prosthesis were delivered with cemented type prosthesis except for single tooth restoration, and the degree of mobility for each implant in such situations was not measured. If implant osseointegration fails, a sense of discomfort or pain at the time of mastication often appears before a radiological change is detected, so it can become one of the first symptom of the implant which fails.^{16,17} In this study, evaluation of the mobility for implants was conducted in general consideration of the symptoms of a patient and clinical and radiographic indicators.

As one of methods for measuring more objectively the stability of the boundary between the implant and the bone, you can use an electrical appliance(Periotest; Siemens, Bensheim, Germany). But in spite of positive reports on this appliance,^{18,19} it is sometime criticized due to lack of sensitivity of values, lack of analysis ability and sensitivity to a variable between operators when it is used for determining early symptom related to implant failure.²⁰ If you use a resonance frequency analysis instrument that measures the strength of the boundary between the bone and the implant (Osstell; Integration Diagnostics, Göteborg, Sweden), it is possible to detect the increase in the movement degree of the implant before a clinical symptom appears²¹, but the decisive data related to the boundary between the bone and the implant and RFA measurements is still insufficient.²² In addition, there exists actual limitation in clinically connecting cement maintenance types of these

instruments and using them for the implant being used.

It seems to be a basis for implant success to maintain the height of marginal bone around an implant for a long-term period. In regards to implant marginal bone loss, there is a report that a basis for bone resorption of 1.5mm for the first year after having the implant placement surgery and after that less than 0.2mm per year was included in the success basis for an implant.^{12,23} As to the most universal type of Brånemark implant, marginal bone applied to the first thread of implant²⁴, 1–2mm of marginal bone was lost in the early first year, and after that an average of 0.05–0.2mm marginal bone continued to be lost each year thereafter. Recently, there is much interest in the effect of micro threads of the upper part of implant fixture on marginal bone response. It was proposed that such micro threads would remarkably reduce peak interfacial shear stress of implant neck region, giving appropriate stimulus to neighboring bone according to Wolff's law. Such principle was applied to the design of Astra implant(Astra Tech AB, Molndal, Sweden). In case of Astra ST implant, there was a report that no marginal bone loss appeared for the early 1 year after insertion of prosthesis, and significant changes in bone appeared for the observation period of 4–5 years.^{26,27,28} After that, other various implant manufacturers began to apply this concept and Implantium® system is one of such implant to which such concept is applied.

With regard to marginal bone loss amounts for 118 Implantium® implants in function for 1 year after implantation, an average of 0.44mm was lost compared with the time immediately after implantation, showing good results. The event where marginal bone was not lost at all or bone loss stopped in the first micro-thread accounted for 53%, which seems to be a result of the combination of micro thread, SLA surface treatment, and load distribution and sealing effects of internal cone type connection structure. However, the best level did not appear in all the cases. In 41% of implants in this study, bone loss of more than 0.3mm and less than 1.5mm appeared. Also, considering that bone loss of less than 1.5mm for the first year and bone loss of less than 0.2mm per year as basis for implant success, 7 implants(6%) among 118 implants used in a radiological study showed marginal bone loss amounts that could be considered as failure. The number of implants for which the causes of

marginal bone loss could be hypothesized was 6: 1 implant whose cover screw was prematurely exposed due to load by temporary denture and used for supporting a bridge having distal extension; and 5 implants of the region where the flap mucosa was open in the early stage while attempting Guided Bone Regeneration technique. In addition, there was 1 implant in the case where the cause of marginal bone loss was difficult to find.

To increase the objectivity of this study that observed survival rate of the implants for short-term periods, continuous additional observation is required. As a periapical radiographic study, there was limitations for measuring marginal bone level. In addition, changes in marginal bone level can be affected by various elements of an implant design among other clinical factors, so that to draw a reliable conclusion, additional observation is required in consideration of more implants and various clinical variables.

(영) V. Conclusion

With 252 Korean made implants which were implanted in 119 patients as subjects, the author observed clinical results for 22 months, evaluated the survival rate of the implants, and also examined the degree of marginal bone loss for the implants for the first year, drawing following conclusions.

1. Regardless of various implantation regions, surgery methods, kinds of prosthesis, the length and diameter of an implant, the osseointegration success rate of Implantium® implant and clinical accumulated survival rate for the period of implant being used(an average of 5.7 months) was 100%.
2. Marginal bone loss of an implant at the time immediately after implantation was 0.16mm(SD 0.30), and marginal bone loss around the implant used in which case 1 year passed after implantation was 0.58mm(SD 0.64). Average loss amount of marginal bone for the first year was 0.44mm(SD0.55).
3. Short-term survival rate of Implantium® implant showed excellent results, but continuous additional observation is required to increase the objectivity of clinical and radiological results.

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