<Original Article>

Prospective Clinical Trial of Survival Rate for Two Different Implant Surfaces Using the Osstem® SS Ⅱ Non-submerged Implant System in Partially Edentulous Patients

Su-Gwan Kim, Chae-Su Lim, Min-Seok Oh,
Jin-Sung Park, Seo-Yoon Kim, Ka-Young Seol

Department of Oral and Maxillofacial Surgery, School of Dentistry,
Chosun University, Gwangju, Korea

Corresponding Author

Su-Gwan Kim, DDS, PhD
Department of Oral and Maxillofacial Surgery, School of Dentistry
Chosun University, 375 SeoSukDong, DongGu, GwangJu City, South Korea
Zip Code: 501-759
Tel. : 82-62-220-3815
Fax : 82-62-228-7316
E-mail : sgckim@chosun.ac.kr

Received for publication Jun 30, 2009; received after revision Aug 26, 2009;
accepted for publication Sep 28, 2009.

• Abstract

Objective : This study sought to investigate the clinical survival rate of two implants with different surfaces: resorbable blasting media (RBM)-treated and calcium metaphosphate (CMP)-coated implant.

Study desi gn : SSII non-submerged implants (Osstem, Seoul, Korea) were placed in a total of 48 patients with mean age of 38.8. At least 31 patients in the experimental group had a CMP-coated implant, and 1 patient in the control group received a, RBM surface implant. The evaluation period was between April 2006 and December 2007. Radiographs, periotest, clinical periodontal examination, and prosthetic adjustment and occlusion were used.

Results : The survival rate of the experimental and control groups after 1 year was 97.2% and 100%, respectively. The Wald confidence interval reported for the experimental group was not inferior to the control group.

Conclusion : No significant differences were found between the RBM and CMP groups. The observed data suggest that CMP-coated methods can provide favorable clinical results for the functioning and healing of dental implants.

• J Kor Dent Sci. 2009; 2(2) : 35 - 41

Introduction

Ongoing research has shown that the surface morphology of the implant is an important factor in accelerating osseointegration[1]. Titanium implants such as Branemark implants have a smooth machined surface. As the oldest type of implants with known excellent biocompatibility and tissue stability, they have been used most commonly[2]. Note, however, that numerous studies are now exploring the effect of different surface treatments of implants on shortening the healing period The variables considered in these studies include the type of implants, expansion of the direct contact surface of the implant and bone, surface roughness, and surface treatment methods[3-5].

Two different surface treatments for increasing the surface roughness of commercially available implants were performed by either blasting with resorbable blasting media (RBM) or coating with calcium metaphosphate (CMP). The RBM surface treatment creates a rough implant surface by spraying biocompatible materials such as oxidated aluminum (Al_2O_3), oxidated titanium (TiO_2), calcium phosphate, and hydroxyapatite powder to the implant surface. In this study, the clinical survival rate of RBM surface implants was compared to CMP-coated implants after a one-year prospective study.

Materials and Methods

Surgery was performed after the patient provided written informed consent. The protocol was approved by the Institutional Review Board (CDIRB2004-1) at Chosun University Dental Hospital prior to its initiation.

Patient Population and Implants Used

A prospective clinical trial was conducted from April 1, 2006 to December 31, 2007 on the 48 patients who visited the Department of Oral and Maxillofacial Surgery of Chosun University Dental Hospital. The patients selected met all the following exclusion criteria:

1. Pregnancy
2. Disease history or recent episode of myocardial infarction
3. Uncontrolled medical diseases
4. Hemorrhagic disease
5. Psychological diseases or patients suspected to have psychological diseases
6. Allergy to implant materials
7. Ethical reasons for exclusion as determined by the investigators

The patients were divided into two groups based on the type of implant surface treatment; 31 patients were assigned to the experimental group (CMP-coated surface), and 17 patients, to the control group (RBM surface). The experimental group consisted of 16 males and 15 females with mean age of 41.2 years. The control group was made up of 10 males and 7 females with mean age of 34.1 years. The gender distribution of the total population was 26 males and 22 females, and the mean age was 38.8 years (Fig. 1).

The assignment of patients to the control group and the experimental group was planned at a 2:1 ratio; every effort was made to assign the subjects without differences in other conditions.

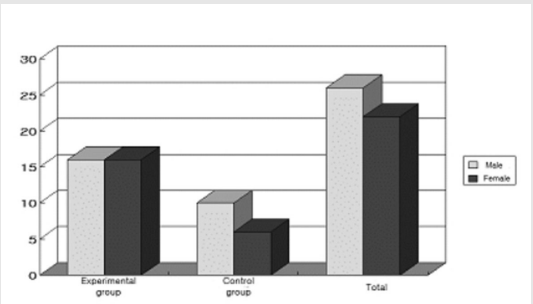

Fig. 1. Age and gender distribution.

The SSII implants (Osstem, Seoul, Korea) used in this study had an internal 8° morse taper connection and a straight body. It was used for the one-stage procedure. Since the screws of the body are triangular with a 0.8 pitch, early stability can be obtained readily in poor bone-quality cases. In addition, the distribution of the masticatory force was good, hence its usefulness in immediate loading. The roughness of the RBM surface was measured to be 1.2 ~ 1.8㎛. The collar area (1.8/2.8) of the implant was treated to create a machined surface, with surface roughness Ra of 0.1 ~ 0.3㎛.

Length and diameter of implants

The experimental group consisted of 31 patients implanted with SSII implants coated with CMP. A total of 36 implants were placed. The control group included 17 patients, with a

Table 1. Implant length and diameter distribution

D / L	8.5mm		10.0mm		11.5mm		13.0mm		15.0mm	
	Experimental group	Control group	Experimental group	Control group	Experimental group	Control group	Experimental group	Control group	Experimental group	Control group
4.0mm										
4.1mm			7	3	6	8	5	2		
4.8mm	2		6		6	3	5		2	1

D : diameter; L : length

total of 20 implants placed. The length and diameter of implants used in this study are shown in Table 1.

Evaluation Methods

Before surgery, the clinical index of surgery area was assessed, and the surgery area was expressed as dentition. The diameter and length of implants were measured. The bone quality was determined by combining the feeling of the drilling procedure of the surgeon and result of panorama radiographs. The findings were classified into 4 types (Types I~IV).

The evaluation of clinical efficacy was based on multiple factors. One of the most important factors for clinical efficacy was zero implant loss or fracture reported. The clinical examination should reveal that implants that were not connected to each other did not move. On radiographs, clinical efficacy was based on penetration imaging in the vicinity of implants on unmodified radiographs. In the evaluation of prosthesis, compatibility/incompatibility was evaluated using articulating paper (approximately 20 ~ 40㎛ thick, Articulating paper BK09, Bausch, Köln, Germany) and shimstock (approximately 8㎛ thick, Altstätten, Switzerland).

For a total of 9 visits over a 12-month period, the following variables were measured: mobility, bone resorption level on radiographs, presence or absence of abnormal reactions, occlusion condition, and patient satisfaction. The specific time intervals for evaluations are shown in the Table 2. At the follow-up examination, the following evaluation methods were used:

a. *Mobility* : This was measured thrice using a Periotest® (Siemens AG, Benssheim, Germany); the average was used as a final value.

b. *Bone Loss* : The amount of bone loss was evaluated by a single reader. Radiographs of the root apex were taken using a parallel method, with the amount of vertical as well as horizontal bone loss measured.

Table 2. Clinical evaluation manual

Number of visits	Observation period*	Observation items & clinical exam. items
Visit 1	-4 week~0 day	Signature on subject consent, Demographic study, Medical history/Dental history taking, Intra ? Extra oral exam., Evaluation of subject suitability, Identification code invest., of subject, Diagnosis impression taking, Panoramic view taking, Clinical index measurement of surgical site
Visit 2	0day(base line)	Implant surgery, Clinical index measurement of surgical site, Mobility check, Allergy reaction check
Visit 3	2 week ± 1 week	Stitch out, Standard view taking, Preliminary impression taking, Allergy reaction check
Visit 4	13week ± 2week (Max.) 7week ± 2week (Man.)	Mobility check, Allergy reaction check
Visit 5	26week ± 2week (Max.) 14week ± 2week (Man.)	Standard view taking, Final impression taking, Allergy reaction check
Visit 6	27week ± 2week (Max.) 15week ± 2week (Man.)	Metal framework try-in, Allergy reaction check
Visit 7	28week ± 2week (Max.) 16week ± 2week (Man.)	Prosthesis setting, Mobility check, Evaluation of occlusal relationship, Allergy reaction check
Visit 8	9month ± 4week (Max.) 6month ± 4week (Man.)	Mobility check, Standard view taking, Allergy reaction check
Visit 8'	9month ± 4week (Man.)	Mobility check, Standard view taking, Allergy reaction check
Visit 9	12month ± 4week (Max.) 12month ± 4week (Man.)	Mobility check, Standard view taking, Evaluation of occlusal relationship, Questionnaire survey of patient satisfaction, Allergy reaction check

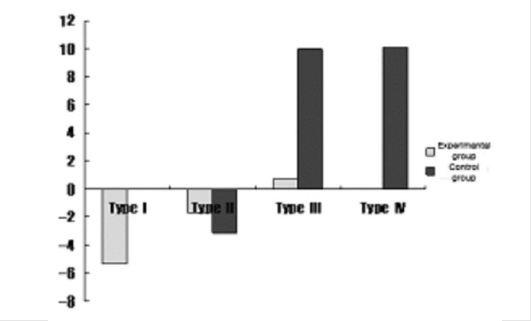

Fig. 2. Mobility test on visit 2.

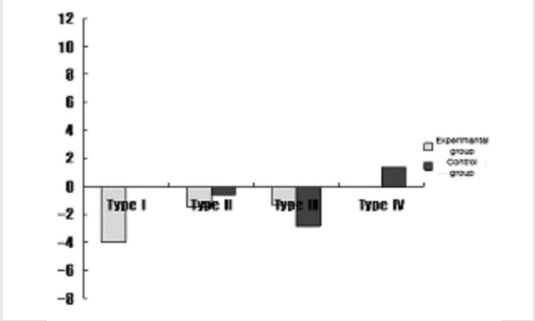

Fig. 3. Mobility test on visit 9.

Su-Gwan Kim et al : Prospective Clinical Trial of Survival Rate for Two Different Implant Surfaces Using the Osstem® SS Ⅱ Non-submerged Implant System in Partially Edentulous Patients

c. *Occlusion* : The evaluation of the occlusal condition after prosthesis was performed at the 7th visit immediately after the placement of the upper structure of the implant (prosthesis). Articulating paper (approximately 20 ~ 40㎛ thick) and shimstock (approximately 8㎛ thick) were used for the evaluation of occlusion.

d. *Abnormal Finding/Reactions* : The incidence of abnormal findings such as hemorrhage, subcutaneous hemorrhage, edema, blood clots, infection, hyperplastic gingivitis, fistula formation, invasions of maxillary and nasal sinus, invasions of mandibular canal, and mental foramen were recorded. Incidence of abnormal reactions such as inflammation in the soft tissue in the vicinity of implants, excessive resorption of marginal alveolar bone, destruction of abutment and other accessories, destruction of implant body as well as prosthesis, mandibular fracture, dysesthesia, and pain and failure of the oral hygiene maintenance were also recorded.

e. *Patient Satisfaction* : On the last visit, a questionnaire on patient satisfaction as developed by the patients was administered. It addressed five areas of concern: occlusal function, pain, discomfort, dysesthesia, and inflammation.

Statistical Analysis

The survival rate of each group was estimated using the maximum likelihood estimator (MLE). To determine the confidence interval of the survival rate, the likelihood-ratio confidence interval was used[6]. The Wald confidence interval and the likelihood-ratio confidence interval were reported as the confidence interval of the difference of the survival rate of the two groups, and their significance was determined[6].

Results

Mobility level according to bone quality

Mobility levels for both groups on the day of surgery was type III and type IV, which suggested that early fixation was not indicated. Note, however, that the final evaluation of the mobility level on all cases showed decreased mobility level with the exception of implants placed in type V bone. This observation suggested that good osseointegration was achieved (Figs. 2, 3).

Mobility level

The difference in mobility level between groups was not statistically significant. Note, however, that the mobility value in the experimental group was smaller than that of the control group. As the observation period spanned 12 months, the mobility level continually decreased compared to the findings reported for the first evaluation (Table 3).

Volume of bone loss

A statistically significant volume of bone loss was not observed in both the control group and the experimental group.

	Group	V2 Mobility	V4 Mobility	V7 Mobility	V8 mobility	V8* Mobility	V9 Mobility
Total	Experimental group(M±S.D)	-1.056 ±3.9078(n=38)	-3.561 ±3.5931(n=38)	-2.740 ±2.5058(n=35)	-2.043 ±2.8440(n=35)	-1.576 ±2.3823(n=17)	-1.628 ±2.3341(n=25)
	Control group (M±S.D)	1.606 ±9.4437(n=18)	-2.811 ±3.3715(n=18)	-1.369 ±3.4869(n=16)	-.973 ±3.2587(n=154)	-1.143 ±2.2963(n=07)	-1.270 ±2.4348(n=10)
	p-value	.364	.461	.116	.249	.679	.688
Mandible	Experimental group(M±S.D)	-2.309 ±3.3081(n=22)	-4.550 ±3.1354(n=22)	-3.082 ±2.5959(n=22)	-1.943 ±3.0214(n=21)	-1.576 ±2.3823(n=17)	-1.523 ±2.2234(n=13)
	Control group (M±S.D)	-.413 ±10.8791(n=08)	-3.650 ±3.2859(n=08)	-1.188 ±3.2140(n=08)	-.314 ±2.5823(n=07)	-1.143 ±2.2293(n=07)	-2.233 ±.6807(n=03)
	p-value	.642	.498	.108	.213	.679	.351
Maxilla	Experimental group(M±S.D)	.669 ±4.1164(n=16)	-2.200 ±3.8301(n=16)	-2.162 ±2.3283(n=13)	-2.193 ±2.6589(n=14)		-1.742 ±2.5429(n=12)
	Control group (M±S.D)	3.220 ±8.3599(n=10)	-2.140 ±3.4565(n=10)	-1.550 ±3.8352(n=08)	-1.550 ±3.8352(n=08)		-.857 ±2.8407(n=07)
	p-value	.307	.968	.659	.647		.493
Statistical analysis : Mobility confirmed at each visit showed no statistical significance(p>0.05) in evaluation of experimental G. and Control G.							

Table 3. Periotest value

Survival rate

The survival rate of the experimental group was 97.2% (95% CI: 91.7 ~ 99.5%), and that of the control group was 100% (94.8 ~ 100%). In the non-inferiority evaluation, by applying the Wald confidence interval, the lower value of the one-tail 95% confidence interval of the difference in survival rate between the groups (survival rate of the experimental group-survival rate of the control group) resulted in a value of -0.0597. In other words, the lower limit of the 95% Wald one-tail confidence interval was larger than the non-inferiority standard of -0.1. Thus, in the comparison of the control group and the experimental group, such was considered to be statistically non-inferior.

On the other hand, the estimation of the survival rate of the experimental group was 0.9722 or close to 1. The survival rate of the control group was estimated to be 1. In such cases, the likelihood ratio confidence interval may be more appropriate than the Wald confidence interval[6]. The result of the lower limit of the one-tail 95 % confidence interval using the likelihood ratio confidence interval was -0.0462; this value was also larger than -0.1 as the standard of non-inferiority. As such, in comparing the experimental group with the control group, the result was statistically non-inferior.

In the comparison of the survival rate of each group according to bone quality (excluding type IV), in Types I ~ III bone, the survival rate of the two groups was estimated to be 100%. Thus, the confidence interval of the difference in the survival rate between the two groups could not be estimated. Nonetheless, this observation suggested that the survival rate of both groups was comparable. In Type IV bone, however, the survival rate of the experimental group was estimated to be 0% (95% confidence interval: 0.0 ~ 61.7%). The survival rate of the control group was estimated to be 100% (95% confidence interval: 61.9 ~ 100%), with a borderline significant difference in the survival rate between the two groups observed.

Discussion

Modifications of implant surface such as coatings with hydroxyapatite[7,8], acid etching[9], blasting[10,11], and sandblasting with larger-grit followed by acid etching (SLA)[12] have been used to increase the surface roughness of commercially available implants. Nonetheless, there are equivocal reports on the effect of these modifications on osseointegration and the success rates. In a rabbit femur study, Piattelli, et al[10] observed more ostoeblasts and mature bones attached to the implants with RBM-treated surface compared to smooth implants 8 weeks after implantation.

Recently, CPM-coated implants have been gaining popularity because of its chemical similarity to bone. Moreover, the degradation byproduct in the biological environments is in the form of fibers[13] or porous rods[14].

CMP has the chemical structure [Ca(PO)3)2]n, and its molar ratio of calcium and phosphate is approximately 0.5. Coating commercially pure titanium with inorganic CMP polymers has been previously reported to be a good candidate technique for improving bone-to-implant osseointegration[15]. Yang[16] reported that the addition of a thin layer of calcium phosphate coating to the implant surface promoted accelerated bone healing around porous-surface implants even after only 2 weeks of initial healing. Lee, et al[17] demonstrated the potential for using a porous CMP matrix as a biodegradable scaffold in vitro along with attached marrow-derived mesenchymal cells for transplantation into a site for bone regeneration in vivo. Experimentally, El Sayegh, et al[14] demonstrated that human gingival fibroblasts could attach to and spread on CMP. Using a rabbit tibia model, Yeo, et al[18] concluded that there were no significant differences in early bone response to calcium metaphosphate-coated, anodic-oxidized, hydroxyapatite particle-blasted, and turned (control) implant surfaces; thus suggesting that various surface modification methods can provide favorable bone responses for the early functioning and healing of dental implants.

Together with the surface characteristic of implants, bone quality in the area of implant placement is also a very important factor in achieving good osseointegration. Lekholm and Zarb[19] classified the bone quality of jaws into 4 grades (from I to IV); this classification method has been commonly used for the classification of bone quality in clinics. Some investigators[20,21] reported a major correlation between the implant success rate and bone quality, with high implant failure rate in cases wherein implants were placed in type IV bone consisting primarily of cancellous bone. Jaffin and Berman[22] reported that Branemark implants placed in type I ~ III bones showed a 97% success rate, whereas implants placed in type IV bone showed a 65% success rate. In other words, bone quality is the most important factor in determining the failure of implants. In addition, Hutton, et al[20] reported that implants placed in type I ~ III bones showed a 91% success rate, whereas implants placed in type IV bones showed a 55% success rate. Similarly, Goodacre, et al[22] and Bryant[23] reported high implant failures in type IV bones and poor bone volumes and bone quality-mediated adverse effects on the stability of implants. Such studies provide evidences on the importance of bone quality in the success of implant. These studies also suggest that placing implants in jaws with good bone quality enables obtaining a high success rate regardless of the type of implants. In this study, the survival rate of both groups studied was highest for type II bone (66.1%), followed by type III bone (25.0%), type IV bone (5.4%), and finally type I bone (1.8%). In addition, in cases excluding type I and type II bone quality at the final evaluation, a reduced level of mobility was observed.

In this study, no significant differences in implant success were found between the RBM and calcium metaphospate coated groups. The data observed in this study suggested that CMP surface modification methods can provide favorable clinical results for the functioning and healing of dental implants.

References

1. Albrektsson T, Zarb G, Worthington P, Eriksson AR. The long-term efficacy of currently used dental implants: a review and proposed criteria of success. Int J Oral Maxillofac Implants 1986; 1: 11-25.
2. Quirynen M, Bollen CM, Papaioannou W, Van Eldere J, van Steenberghe D. The influence of titanium abutment surface roughness on plaque accumulation and gingivitis: short-term observations. Int J Oral Maxillofac Implants 1996; 11: 169-178.
3. Pillar RM. Porous-surfaced metallic implants for orthopedic application. J Biomed Mat Res 1987; 21: 1-33.
4. Botticelli D, Berglundh T, Persson LG, Lindhe J. Bone regeneration at implants with turned or rough surfaces in self-contained defects. An experimental study in the dog. J Clin Periodontol 2005; 32: 448-455.
5. Buser D, Schenk RK, Steinemann S, Fiorellini JP, Fox CH, Stich H. Influence of surface characteristics on bone integration of titanium implants. A histomorphometric study in miniature pig. J Biomed Mat Res 1991; 25: 889-902.
6. Agresti A: Categorical Data Analysis, 2nd ed. Hoboken: Wiley; 2002.
7. Cook SD, Kay JF, Thomas KA, Jarcho M. Interface mechanics and histology of titanium and hydroxyapatite-coated titanium for dental implat applications. Int J Oral Maxillofac Implants 1987; 2: 15-22.
8. Block MS, Kent JN, Kay JF. Evaluation of hydroxyapatite-coated titanium dental implants in dogs. J Oral Maxillofac Surg 1987; 45: 601-607.
9. Trisi P, Lazzara R, Rao W, Rebaudi A. Bone-implant contact and bone quality: Evaluation of expected and actual bone contact on machined and osseotite implant surfaces. Int J Periodontics Restorative Dent 2002; 22: 535-545.
10. Piattelli M, Scarano A, Paolantonio M, Iezzi G, Petrone G, Piattelli A. Bone response to mechined and resorbable blast material titanium implats: an experimental study in rabbits. J Oral Implantol 2002; 28: 2-8.

References

11. Sanz A, Oyarz?n A, Farias D, Diaz I. Experimental study of bone response to a new surface treatment of endosseous titanium implants. Implant Dent 2001; 10: 126-131.
12. Cochran DL, Buser D, ten Bruggenkate CM, Weingart D, Taylor TM, Bernard JP, Peters F, Simpson JP. The use of reduced healing times on ITI implants with a sandblasted and acid-etched(SLA) surface: early results from clinical trials on ITI SLA implants. Clin Oral Implants Res 2002; 13: 144-153.
13. Kasuga T, Ota Y, Nogami M, Abe Y. Surface modification of calcium metaphosphate fibers. J Mater Sci Mater Med 2000; 11: 223-225.
14. El Sayegh TY, Pilliar RM, McCulloch CA. Attachment, spreading, and matrix formation by human gingival fibroblasts on porous-structured titanium alloy and calcium polyphosphate substrates. J Biomed Mater Res 2002; 61: 482-492.
15. Kim SG, Oh DS. Placement of calcium metaphosphate-coated dental implants in the posterior maxilla: case reports. Hosp Dent (Tokyo) 2008; 20: 39-43.
16. Yang C. The effect of calcium phosphate implant coating on osteoconduction. Oral Surg Oral Med Oral Pathol Oral Radiol Endod 2001; 92: 606-609.
17. Lee YM, Seol YJ, Lim YT, Kim S, Han SB, Rhyu IC, Baek SH, Heo SJ, Choi JY, Klokkevold PR, Chung CP. Tissue-engineered growth of bone by marrow cell transplantation using porous calcium metaphosphate matrices. J Biomed Mater Res 2001; 54: 216-223.
18. Yeo IS, Han JS, Yang JH. Biomechanical and histomorphometric study of dental implants with different surface characteristics. J Biomed Mater Res B Appl Biomater 2008; 87: 303-311.
19. Lekholm U, Zarb GA. Patient selection and preparation. In: Brenemark PI, Zarb GA, Albrektsonn T. Tissue Integrated prostheses: Osseointegration in Clincal Dentistry. Chicago. Quintessence publishing Co. 1985; 199-209.
20. Hutton JE, Heath MR, Chai JY, Harnett J, Jemt T, Johns RB, McKenna S, McNamara DC, van Steenberghe D, Taylor R. Factors related to success and failure rates at 3-year follow-up in a multicenter study of overdentures supported by Brenemark implants. Int J Oral Maxillofac Implants 1995; 10: 33-42.
21. Jaffin RA, Berman CL. The excessive loss of Branemark fixtures in type Ⅳ bone: A 5-year analysis. J Periodentol 1991; 62: 2-4.
22. Goodacre CJ, Kan JY, Rungcharassaeng K. Clinical complications of osseointegrated implants. J Prosthet Dent 1999; 81: 537-552.
23. Bryant SR. The effect of age, jaw site, and bone conditions on oral implant outcomes. Int J Prosthodont 1998; 11: 470-490.