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Research Article

Ten Years Follow-Up of Sputtered Hydroxyapatite Coated Implant in Single or Two Missing Teeth Replacement

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Abstract

Sputtered hydroxyapatite coated implant has investigated as an implant with novel surface coating for dental implant. The aim of this study was to evaluate the 10 years clinical outcome regarding marginal bone loss around implants, success rate, survival rate, biological and prosthetic complication and patients subjective satisfaction for the implant with sputtered hydroxyapatite coating in human. Sixteen patients with 30 implants were employed for this study. One-piece, sputtered hydroxyapatite coated implants were placed in premolar and/or molar sites with one or two missing tooth. Ten years after implant placement, the marginal bone level change was evaluated by per apical radiograph. Incidence of peri-implant diseases and prosthetic complications were also addressed. Patient satisfaction was analyzed by Oral Health Impact Profile questionnaire. The mean marginal bone loss was 0.74 ± 1.41 mm. Survival and success rates were 96.7% and 86.7% respectively. Three implants (10.0%) in 3 patients (18.8%) were affected by peri-implantitis. Five implants (16.7%) in 4 patients (25%) had chipping of veneering material on prosthesis. One implant (3.3%) in a patient (6.3%) was fractured and removed. Mean score of Oral Health Impact Profile was 41.6 ranged from 3 to 89. Sputtered hydroxyapatite surface showed comparable marginal bone stability in 10 years result. (198 words)

Keywords: Clinical evaluation, Dental implants, Hydroxyapatite, Implant surfaces, Crestal bone loss, Long-term results.

Introduction

Dental implant has been widely accepted as a predictable prosthodontics treatment option for replacing missing teeth [1,2,3].Osseointegration is characterized by clinical stability of a functionally loaded implant and it is mandatory for success of this treatment [4].

Several kinds of surface modification have been developed to achieve fast and reliable osseointegration [1,5]. Although subtractive modifications such as sandblasting and acid-etching preparation are predominant among the commercially available implants, coating with hydroxyapatite (HA) layer on the surface of implant have been alternatively attempted to enhance the osseointegration [6,7]. Researchers have found that as the chemical and physiological property of hydroxyapatite mimics the bone mineral, firm osseointegration expected to be achieved in a short period of time [8]. Therefore, it is used for several kinds of commercially available implants.

Plasma sprayed coating has dominated the coating method for HA surface dental implant. With this method, the thickness of HA layer is made up to 50 µm. This is so thick that the detachment of HA layer might be anticipated thus it possibly might be a source of infection thereafter [9]. To get rid of these shortcomings, technique to produce thinner hydroxyapatite layer have been investigated.

Radiofrequency magnetron sputtering is the depositing method to create uniform 1-2µm hydroxyapatite layer on the surface of titanium implant. This layer is firmly attached to the titanium surface without deteriorating microstructure of implant surface. Animal studies have shown that SHA coated implants have favorable clinical outcomes without deteriorating peri-implant tissue health [10] Moreover, Ozeki et al reported their canine model experiment that after 12 weeks of implant placement, the thickness of the HA layer decreased from 1µm to 0.4 ± 0.03 µm so the HA layer is expected to be disappeared after longer period of time [11]. However, there have been no data for long-term human study. Ten years have passed since the first prototype of one-piece implant with SHA coating applied to patients. The aim of this study was to evaluate the 10 year clinical outcome regarding crestal bone loss (CBL) around implants, success rate,

survival rate, biologic and prosthetic complication and patients subjective satisfaction with the SHA coated implant.

Materials and Methods

Patient selection

Although this clinical trial employed 41 patients in the beginning, 25 patients dropped out from a supportive care due to patients' circumstances during 10 years. Therefore, we disclose data of 16 patients with 30 implants whom we could follow up 10-year outcome.

Patients of age between 20-70 with single or two missing teeth/tooth who willing to be restored with implant prosthesis were employed. The alveolar ridge should have enough amount of bone to accommodate required number of implants without any bone grafting procedures, i.e. the bucco-lingual width needs more than 5 mm, the bone height toward maxillary sinus or mandibular canal is more than 12 mm and the distance between implant and neighboring teeth are more than 2 mm at medially and distally. All the patients performed proper oral hygiene. Patients with severe systemic disease (heart disease, uncontrolled diabetes, immune deficiency liver disease etc.), metabolic bone disease, history of severe periodontitis, xerostomia, severe skeletal malocclusion or Pregnancy are excluded from this clinical trial. Inclusion and exclusion criteria are summarized in (Table 1). Between January and June 2005, patients were employed in Implant Clinic of Dental Hospital at Tokyo Medical and Dental University. All patients provided informed consent in written form to participate in this trial. Patients were evaluated in the university's dental clinic. Detailed oral examinations and radiographic evaluations including panoramic and CT scan were performed. Any pre-existing dental pathologies were treated or eliminated before implant surgery.

Inclusion and exclusion criteria	
Inclusion criteria	One or two missing tooth/teeth in premolar or molar site Enough alveolar bone (>5 mm width, >12 mm hight, 2mm from mesial and distal teeth) The age between 20 to 70 yrs Proper oral hygiene
Exclusion criteria	Severe systemic disease (heart disease, uncontrolled diabetes, immune deficiency liver disease etc) Metabolic bone disease History of severe periodontitis Xerostomia Severe skeletal malocclusion Pregnancy

Table 1: Inclusion and exclusion criteria

Implant

This clinical trial used one-piece implant made of pure grade IV titanium (Prototype of μ-One implant, Yamaha chi Dental MFG Co, Aichi Japan). It has smooth surface at built-in abutment and transmucosal part and rough surface with sputtered hydroxyapatite coating on its intraosseus part. Squared single thread spirals around its parallel-shaped body. In this clinical trial, diameter of 3.7 or 4.0, length of 8 or 10 mm was utilized. The macro and micro images of this implant is shown in (Figure 1).

Figure 1: Macro and micro (SEM) images of SHA coated implant. SEM image shows magnification of rough surface.

Surgery and Prosthetic Procedures

Surgeries were carried out under local anesthesia by one of five experienced surgeons in the clinic. All implants were placed using a standardized surgical procedure after a midcrestal incision and mucoperiostal flap elevation on the buccal and lingual aspects. The SHA coated implants were placed until the junction of smooth and rough surface reach the level or 1 mm below the alveolar crest, without any grafting procedure. As this implant has a built-in abutment, non-submerged healing protocol was conducted. Postoperative antibiotic prophylaxis was provided for 3-5 days after surgery (cefcapene pivoxil or, in case of allergy, clindamycin). Sutures were removed 7-14 days after surgery. Cement retained definitive prosthesis (metal-ceramic crown) were delivered with temporary cements and implants were loaded 2 months after the implants placed in the mandible and after 4 months in the maxilla. Patients had received continuous supportive therapy every 6 months.

Evaluation

The first endpoint was crestal bone loss (CBL) around implants were measured by comparing periapical intraoral radiograph taken just after implant surgery and 10 years after surgery. One radiologist performed radiographic interpretation and measurements. The average of mesial and distal CBL was figured out as a representative value of CBL. Second endpoint was other clinical parameters such as presence of peri-implant disease, prosthetic complications, survival and success rates were evaluated. The definition by Zitzmann et al was employed as a criteria for diagnosing peri-implantitis [12]. Success rate was figured out according to the criteria by Buser et al [13]. Patients satisfaction were analyzed by Oral Health Impact

Profile (OHIP) questionnaire at the time of 10-year observation [14].

Results

Healing period

After surgery, patients reported none or little discomfort. No post-surgical complications were reported. Oral hygiene was well maintained by all patients.

Radiographic Evaluation

No signs of continuous radiolucency were detected. Between the baseline and the 10-year evaluations, the CBL demonstrated a mean loss of 0.78 ± 1.41mm. Some implants had higher level of marginal bone compared with the baseline. Each patients' CBLs were shown in (Figure 2). Intraoral radiograph of implant with stable bone level were shown in (Figure 3a-3b).

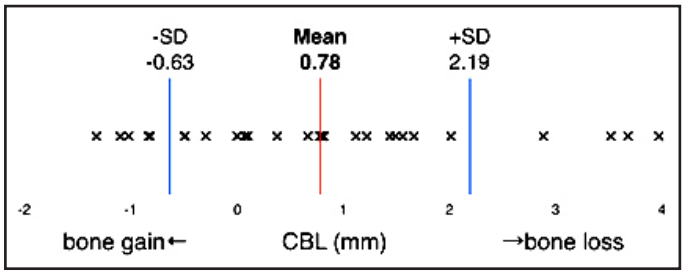

Figure 2: CBL in each implant after 10 years

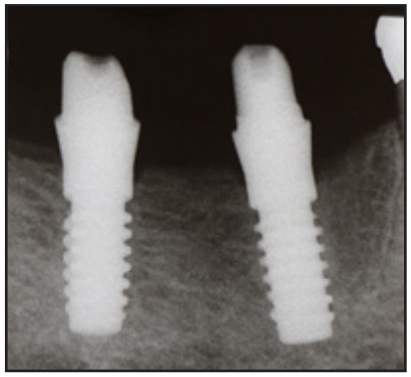

Figure 3a: Intraoral radiograph of one patient just after the implant placement.

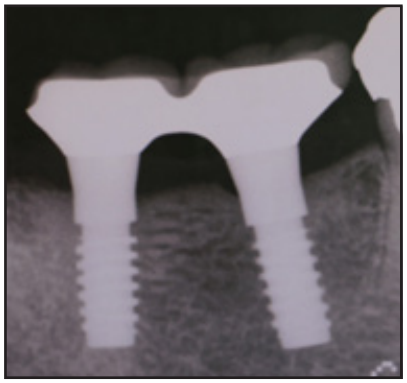

Figure 3b: Intraoral radiograph of the same implants to Fig. 3a after 10 years exhibits stable marginal bone level.

Biological Complication

Three implants in 3 patients revealed inflammatory symptom such as bleeding on probing or suppuration associated with marginal bone loss i.e. peri-implantitis. Intraoral radiograph of implant with peri-implantitis were shown in [Figure 4a-4b].

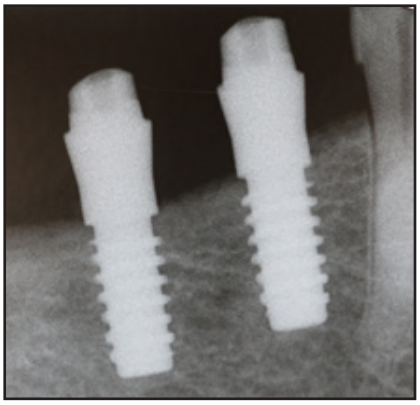

Figure 4a: Intraoral radiograph of one patient just after the implant placement

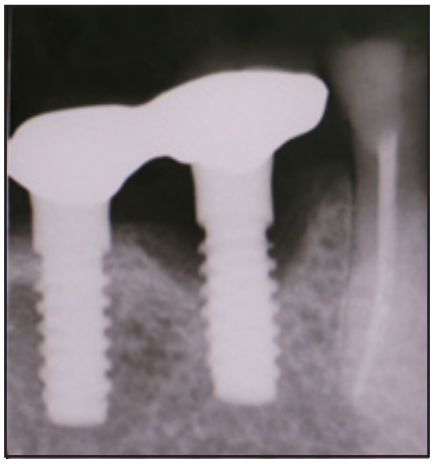

Figure 4b: Intraoral radiograph of the same implants to Fig. 4a after 10 years exhibits significant bone loss accompanied by peri-implantitis.

Prosthetic Complication

Minor veneered porcelain chipping were detected in 5 implants in 4 patients. One implant was fractured therefore it was surgically removed. The patient received another type of implant after bone healing.

Survival and Success rates

One implant in one patient was removed due to the implant fracture therefore survival rate was 96.7%. Three implants affected by peri-implantitis excluded from the success implant hence success rate was 86.7%.

Patients' satisfaction and Social impact

Average score of OHIP was 41.6. The minimal value was 3 and the maximal value was 89. Among 0-212, the smaller implies the better satisfaction of patients. Standard deviation (SD) was 24.8.

The prevalence of biologic and prosthetic complications, survival and success rates and OHIP score are summarized in (Table 2).

Clinical Parameters after 10 years	
Mean CBL	0.78 ±1.41mm (Min:-1.3, Max:4.0)
Median CBL	0.78 mm
Peri-implantitis	3 implants (10.0%), 3 patients (18.8%)
Porcelain Chipping	5 implants (16.7%), 4 patients (25.0%)
Implant fracture	1 implant (3.3%), 1 patient (6.3%)
Survival rate	96.70%
Success rate	86.70%
Average OHIP Score	41.6 (Min:3, Max: 89)
	The smaller the better among 0-212

Table 2: Clinical Parameters after 10 years

Discussion

In this study we examined 10-year results of spattered hydroxyapatite coated implant with regard to CBL, survival rates, success rates, incidence of biologic or prosthetic complications and patient's subjective satisfaction.

In this study the mean CBL was 0.78 ± 1.41mm in 10 years. Schwartz-Arad et al reports in their 10-year retrospective analysis that HA coated implant has 1.51 ± 2.71mm CBL, which is greater than pure titanium implant that had 0.55 ± 1.04 mm CBL. [15] Matarasso et al compare the 10-year peri-implant bone loss rate in periodontal compromised (PCP) and periodontal healthy patients (PHP) around two different implant systems (Branemark implants and Straumann Dental Implant System) supporting single-unit crowns. The mean bone loss ± SD amounted to 2.78 ± 0.48- 1.95 ± 0.42mm in the PCP and PHP group with Branemark implants, respectively (Po0.0001). In the group with Straumann implant, the mean bone loss ± SD was 2.32 ± 0.41 and 1.43 ± 0.38mm in the PCP and PHP group, respectively [16]. Zuffetti et al evaluated 10 years result of immediate or early loaded implant placed to replace single or multiple missing teeth. After 10 years, immediately loaded patients lost an average of 1.34 mm and early loaded patients lost 1.42 mm of peri-implant marginal bone. Comparing to these results, it would be concluded that the result of present study shows relatively favorable bone stability for 10 years period of time. However, Blanes et al reported crestal bone loss around ITI dental implants placed in the posterior region of partially edentulous patients. The total crestal bone loss was 0.24 ± 1.16mm and this result is significantly lower than the other studies cited above [17].

In some cases, marginal bone level grew compared to the first stage. Buser et al reports CBL changes around ITI implant with TPS surface between 1year and 8 years after the implant placement. CBL change between 0.01 and 0.71 mm of bone gain was predominant. There are other several literatures reports the same phenomenon especially when one-piece type of implant was utilized.

According to the success criteria presented by Albrektsson et al, annualy less than 0.2 mm vertical bone loss is considered as success [18]. Misch et al proposed another success criteria in ICOI meeting in Pisa in 2007 as less than 2 mm radiographic bone loss from initial surgery is considered as success [19]. According to these success criteria, the 25 of 30 implants in this study exhibited marginal bone loss within the range of norm, and the average of CBL is absolutely lower than the threshold of success criteria.

It is considered that HA coated implants have higher potential for infection than subtractive surface modification. Marwa et al evaluated the amount of bone loss when 4 different surfaces-machined, sandblasted acid-etched, 1-lμm thin sputter hydroxyapatite coated, and plasma- sprayed HA-coated-were in the mandibles of beagle dog [10].

Plasma-sprayed HA-coated implants showed larger peri-implant defects than the other three surfaces. In addition to that, the same author carried out another study comparing four kinds of surface modification: machined, sandblasted/ acid-etched, 1-μm thin sputter HA-coated, and plasma-sprayed HA-coated placed in dog mandible. After a 4-month period of active breakdown Radiographic marginal bone levels, probing depths, clinical attachment levels, and modified Gingival Index were evaluated. There was no significant increase for the degree of peri-implantitis progression around the SHA coated implant as well.

Mombelli et al reported that peri-implantitis seems to be in the order of 10% implants and 20% patients during 5 -10 years after implant placement [20]. These numbers are quite similar to the result of this study, which revealed 10.0% of implant and 18.8% of patients with peri-implantitis. Therefore, the prevalence to the peri-implantitis seems the same degree to the non-apatite coated implant. This result indicates the same susceptibility between HA coated implant and implants with other surface modification.

Ozeki et al reported their canine model experiment that after 12 weeks of implant placement, the thickness of the HA layer decreased from 1μm to 0.4 ± 0.03 μm [11]. Piattelli et al reported the HA layer lessening in implant placed in human bone after 12 months of surgery [21]. There is a prospect that the HA layer of this implant have almost or completely disappeared during the 10 years period of time and this might prevent the deteriorating effect of HA coating. Further study is required to confirm the diminishing phenomenon in the future.

Conclusion

Within the limitation of this study, SHA coated implant exhibited

stabilized peri-implant tissue and high survival rate compared to other study reporting 10 years follow-up. Slightly higher complication rates might be attributed to the limited number of patients and implants involved in this study. SHA coating could be a favorable surface modification to achieve long-term stability of marginal bone level.

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