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Original article

Retrospective clinical outcome of nanopolymorphic crystalline hydroxyapatite-coated and anodic oxidized titanium implants for 10 years

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ABSTRACT

Purpose: Nanopolymorphic crystalline Hydroxyapatite (HA)-coated implants were different in surface property from conventional HA-coated implants subjected to previous clinical studies. The purposes of the present study were to retrospectively evaluate 10-years clinical outcome of the HA-coated implants (HA implants) with a comparison to the same system implants with anodic oxidized titanium surface (Ti implants).

Methods: Cumulative survival rate (CSR) of HA or Ti implants placed in 183 patients (55 ± 12.4 years old) over two decades was calculated with life table analysis. Differences in CSR at each interval year, sex, age, frequency of number of implant placement according to implant location and diameter were compared between both types of implants.

Results: Total 455 HA implants and 255 Ti implants were included. CSR at upper molar site was consistently higher in HA implants than Ti implants until 8 years after placement. The values after 10 years was 89.9% or 77.7% in HA or Ti implants, respectively. There were no significant differences in overall CSR at any interval year. HA implants were more distributed at upper molar site but less at lower molar site than Ti implants. Diameter of HA implants tended to be wider than Ti implants.

Conclusions: Under limitation of this retrospective study, the nanopolymorphic crystalline HA-coated implants were more survived at upper molar site than anodic oxidized implants until 8 years after placement. This clinical outcome might attribute to differences in topographical and physicochemical characteristics between both types of implants.

1. Introduction

Hydroxyapatite (HA)-coated implants had been introduced as "bio-active" implants overwhelming "bio-inert" titanium (Ti) implants in 1980s [1,2]. The surface has been recognized as "the first generation implant" [3] even as titanium plasma-sprayed (TPS) surface. There have been controversies about their definite role in acquirement and maintenance of the bone–implant integration as coating material onto implants.

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Some clinical studies reported that HA-coated implants have a concern in the long-term stability and prognosis [4–7]. The report pointed out that HA-coated implants had the higher sensitivity for peri-implantitis than those in Ti surface implants [8]. In addition, there were little direct evidences about critical advantage of osseointegration capability as compared to micro-roughened titanium surfaces which is representative currently available titanium surface ensuring substantial clinical stability [5–7,9–11].

HA has a multiple of physicochemical properties. HA structurally has both positively and negatively charged planes (a and c planes, respectively) by calcium and phosphate ions in the crystalline structure. The solubility of HA is known to be markedly lower than that of the other calcium phosphate materials such as tri-calcium phosphate. However, the solubility of HA is changed by the crystalline and the calcium/phosphorus (Ca/P) ratio. For example, stoichiometric HA, which has a 1.67 Ca/P ratio, is not soluble in water and shows the highly solid mechanical property [12]. If going far from 1.67 in Ca/P ratio, the HA has greater water-solubility and lower mechanical property due to a deficits of crystalline structure [12]. In contrast, such non-stoichiometric HA with water-solubility chemically interacts with osteogenic cells and the local environment by releasing ions necessary for bone formation. By this mean, the different HA-implants manufactured by the different process cannot be considered to exert the same clinical performance.

In addition to inherent physicochemical property of HA, surface topography also influence the osseointegration capability. This fact makes the interpretation of one HA surface very difficult. Most of reports about long-term clinical outcomes of HA implants had been intended for high-temperature-sintered HA coating method including plasma-spray technology which requires fusing HA at very high temperatures of 10,000–20,000 °C. It is known that high-temperature-sintered HA implants generally exhibit relatively large-scale surface topography in sub-milli scale but not in microscale or nanoscale [13–19]. Such HA-coating is solid and non- or less soluble in water but relatively thick (several dozen micron or more) and fragile [20]. This suspected as a cause of exfoliation within coating layer and delamination at coating-titanium substrate interface after functional loading.

Recently, nanopolymorphic crystalline HA-coating was established using a combination of flame spray and low-temperature calcination. In this method, HA was sprayed at 2700 °C which was markedly lower than that in plasma spray. It was reported that this coating method achieved both a layer of HA with a nearly stoichiometric Ca/P ratio (1.66) and a biomimetic needle-like crystalline architectures on micron-roughened titanium surface [21]. The nano-structures might enhance osteoblastic adhesion, proliferation and differentiation via stimulation of focal adhesion kinase [22,23]. This distinct characteristic is never seen in the other HA-coating methods including plasma spray or biomimetic apatite formation using simulated body fluid [24]. Enhancement of osseointegration capability by this HA-coating was evidenced in rat femur model [21]. However, clinical outcomes, in particular, long-term survival of this HA-coating implants never been reported. The purposes of the present study were to retrospectively evaluate over 10-years clinical outcome of commercially available implants with the nanopolymorphic crystalline HA-coating on sandblasted surface with a comparison to the same system implants with anodic oxidization on the same micron geometry.

2. Materials and methods

2.1. Implants

This study dealt with two types of clinically available implants with anodic oxidized titanium surface (Ti implants, FINAFIX, Kyocera Medical, Osaka) and HA-coated surface (HA implants, FINATITE, Kyocera Medical). The representative macroscopic images of both types of sample implants were shown in Fig. 1a and b, respectively. Images under scanning electron microscopy (SEM; SU-6600, Hitachi, Tokyo, Japan) and the arithmetic mean surface roughness (Ra) determined with a 3D measuring laser microscope (LEXT OLS4000, Olympus, Tokyo, Japan) were shown in Fig. 1b–h. Ra values were determined by five arbitrary points of implant surface using a cut-off value of 8 μm and measurement length of 130 μm. Ti and HA implants was launched at 1990 and 1995, respectively.

After the release of HA implants, each type of implants was clinically selected based on clinical determination. Implant selection was nearly depended on the clinical judgment based on the management for the bone quality and occlusal loading. For example, HA implants were favorably used in the cases that the surgeon felt the difficulty of the implant initial fixation due to poor bone quality and that patients wanted the shortened healing periods as much as possible. In contrast, Ti implants were favorably placed into well-mineralized and solid bone which had concerns for exfoliation of HA-coating during insertion.

2.2. Subject

One hundred eighty three patients (an average age of 55 ± 12.4 years at first visit) were subjected for this retrospective observation study. They had visited Kato dental clinic Implant Center of Nakameguro for 20 years (from 1993/7/1 to 2013/12/31) and underwent implant placement from 1993/7/26 to 2003/12/3 at the clinics. Patients with severe systemic disease and markedly poor compliance for dental treatment such as severe diabetes, osteoporosis, rheumatism, high pressure, psychogenic illness, extremely poor plaque control, heavy smoker and other psychogenic and physical characters non-adapted for implant therapy. All patients underwent informed consent for dental implant therapy after consultation about advantage, disadvantage and requirements of various prosthodontic treatments. All patient records were treated as data for retrospective observation study according to the guideline for clinical study established by the Ministry of Health, Labour and Welfare in Japan. Notifications about use of patient's medical and dental records for this epidemiology study under personal information protection were displayed in the clinics. Birthday, sex, first and last visit date, dates of implant placement and lost, implant length and diameter, bone quality records based on traditional classification by Lekholm and Zarb [25], presence or absence of bone augmentation such as maxillary sinus augmentation or guided bone regeneration

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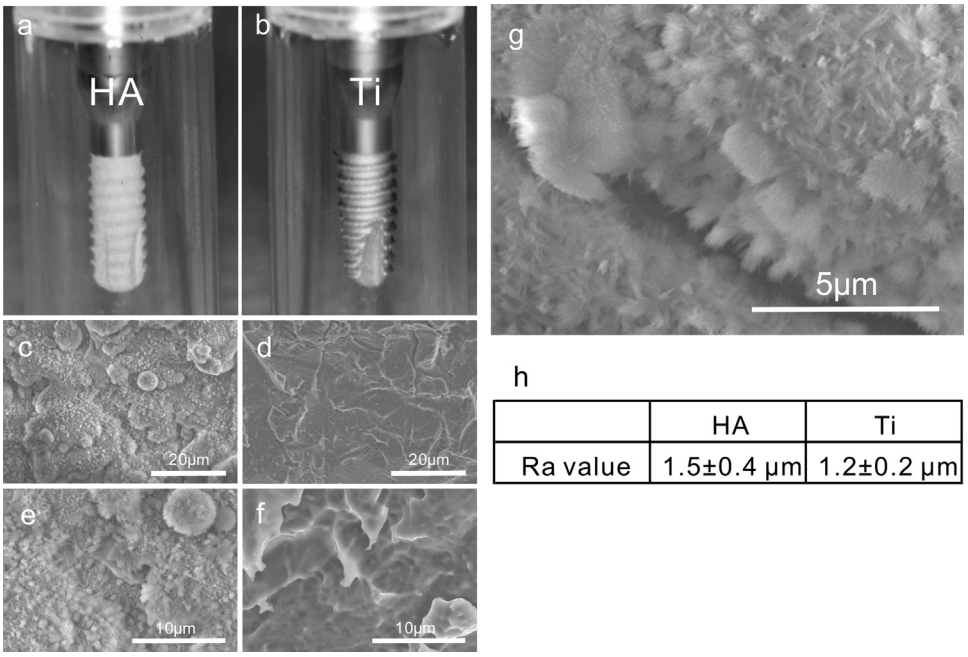

h

	HA	Ti
Ra value	1.5±0.4 μm	1.2±0.2 μm

Fig. 1 – Photographs of scanning electron microscopic images nanopolymorphic crystalline HA-coated (a, c, e and g) or anodic oxidized (b, d and f) implants. Arithmetic mean estimation (Ra) values measured with laser microscopy are no significant difference between both types of implants (h).

and surface type and peripheral X-rays were extracted from all patient medical records and analyzed after linkable anonymization. The surgeon was certified as a dental implant specialist by Japanese Society of Oral Implantology in 2013. This study protocol was approved by the Ethical Committee of Tokyo Dental College (receipt number: 569).

2.3. *Statistical analysis*

Difference in sex and frequency of number of implant placement according to implant location and diameter were evaluated between both types of implants with Chi-square test with residual analysis. Difference in distribution of number of implant placement according to years and the average age of patients were evaluated between both types of implants with *F*-test and Mann–Whitney *U*-test, respectively. Cumulative survival rate (CSR) of both types of implants was calculated with life table analysis of Cutler–Ederer method according to group as a whole, implant location and diameter. Difference in CSR at interval year between both types of implants evaluated with z-test. All statistical analysis was performed using a commercial statistical computer program (SPSS Standard Version, SPSS Japan, Tokyo, Japan) and a commercial spreadsheet software (Microsoft Excel 2010, Microsoft Japan, Tokyo, Japan). Statistical significance was set at $p < 0.05$.

3. Results

3.1. *Implant's characteristics*

Ti implants (Fig. 1b) showed sunny yellow color in contrast with bluish white color of HA-implants (Fig. 1a). Those implants were similar in implant shape such as body contour, thread width, depth and number, interval of pitches and self-tapping design (Fig. 1a and b). Their surface morphologies of titanium substrate at micron level were similar, which was characterized by irregularities across a couple of dozen micron millimeter scale (Fig. 1c and d). In fact, there was no significant difference in Ra value under above mentioned measurement condition between both types of implants (HA: 1.5 ± 0.4 μm; Ti: 1.2 ± 0.2 μm) (Mann–Whitney *U*-test) (Fig. 1h). However, surface morphology at submicron level was totally different between those implants. Only moderate edges like burr after sandblasting and some concavities on floor were observed in Ti implants (Fig. 1f). In contrast, HA implant surface showed distinct nanopolymorphic structure, where nano-needle like structures closed up and formed clusters in spots (Fig. 1e and g).

3.2. *Patients and implant location and diameter distributions*

Total 255 Ti implants and 455 HA implants were placed (Fig. 2). There were no statistical differences between both types of implants in sex and age at implant placement (Fig. 2). Most number of implants were placed molar sites (premolar to molar) in both types of implants. There were significant differences between both types of implants in frequency of number of implant placement at upper and lower molar sites (asterisks in Fig. 2), but no significant differences at incisor site regardless of maxillomandibular alveolar ridge. A 4.2 mm diameter implants were the most frequently placed in both types of implants, whose ratios to total number were approximately 60% (Fig. 2). The next most frequent diameter was 3.7 mm diameter, which was 20.9% and 32.0% in ratio to

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Surface type		HA	Ti
Total number		455	255
Sex ratio (male/female)		0.6	1.7
Age at surgery (years)		52.1±12.5	52.5±11.9
Ratio of implant location	Upper incisor	17.8%	12.5%
	Upper molar ★	39.1%	22.0%
	Lower incisor	2.2%	2.7%
	Lower molar ★	40.9%	62.7%
Ratio of implant diameter	3.2mm ★	2.9%	6.5%
	3.7mm ★	20.9%	32.0%
	4.2mm	59.1%	61.5%
	5.5mm ★	17.1%	0%
Ratio of implant length	< 10mm	3.6%	3.1%
	10—12mm	88.1%	81.3%
	12mm >	8.3%	15.6%
Bone quality 4 ★		56.9%	33.3%
Ratio of sinus floor augmentation		19.0%	14.3%
Ratio of GBR		20.2%	20.4%

Fig. 2 – General information about total implant number, patient's sex ratio, average age and incidents of bone quality 4 and bone augmentation therapy such as sinus floor augmentation and guided bone regeneration at implant surgery, ratio of implant location, diameter and length of nanopolymorphic crystalline HA-coated or anodic oxidized implants. ★$p < 0.05$, significant difference between both types implants (Chi-square test).

total number. Ti implants did not have 5.5 mm diameter. There were significant differences between both types of implants in frequency of number of implant with 3.2, 3.7 and 5.5 mm diameter (asterisks in Fig. 2) and in frequency of bone quality 4 at implantation sites, which based on Lekholm and Zarb classification. However, there were no significant differences in implant length and frequency of bone augmentation procedure such as maxillary sinus augmentation and guided bone regeneration.

Ti implants and HA implants were placed from 1993 to 2003 and from 1995 to 2004, respectively (Fig. 3). Majority of placement was concentrated from 1998 to 2002 in Ti implants and from 2001 to 2003 in HA, respectively. Distribution of number of implant placement according to years showed unequal variance in both types of implants and significant difference between the types of implants.

3.3. *CSR according to group as a whole, molar site and diameter*

Life table analysis revealed that CSR in HA implants were 98.4%, 94.5% and 90.2% at a 0–1, 4–5 and 9–10 interval year, respectively (Fig. 4a and b). The values in Ti implants were 96.3%, 91.9%, and 89.2% (Fig. 4a). Implant numbers included for

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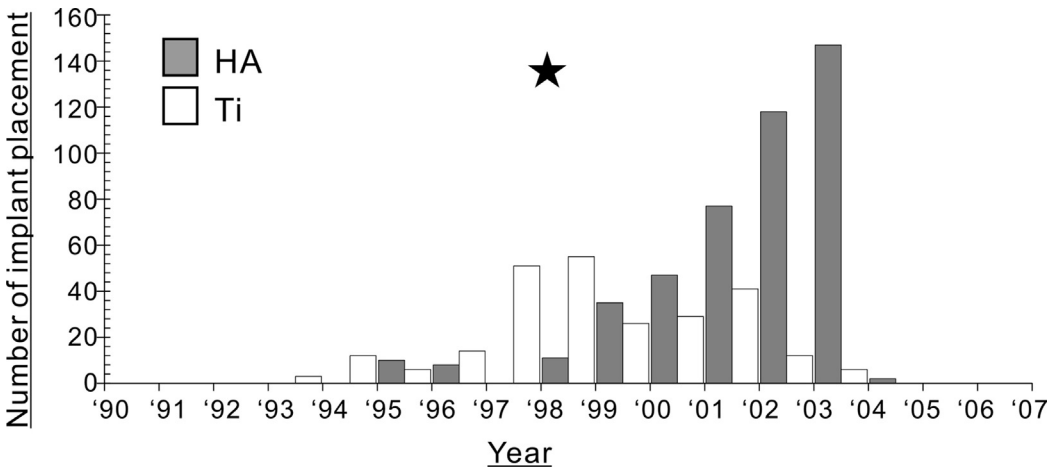

Fig. 3 – Distribution of number of implant placement according to years. ★$p < 0.05$, significant difference between both types implants (*F*-test).

a

HA surface	Interval (years)									
	0-1	1-2	2-3	3-4	4-5	5-6	6-7	7-8	8-9	9-10
N	455	435	410	392	375	361	346	322	305	283
Failure	7	5	3	3	5	6	2	1	5	1
Withdraw	13	20	15	14	9	9	22	16	17	9
Survival rate	98.4%	98.8%	99.3%	99.2%	98.7%	98.3%	99.4%	99.7%	98.3%	99.6%
CSR	98.4%	97.3%	96.6%	95.8%	94.5%	92.9%	92.4%	92.1%	90.5%	90.2%
SD (±)	0.6%	0.8%	0.9%	1.0%	1.1%	1.3%	1.4%	1.4%	1.5%	1.6%

Ti surface	Interval (years)									
	0-1	1-2	2-3	3-4	4-5	5-6	6-7	7-8	8-9	9-10
N	255	229	218	207	201	196	191	170	158	151
Failure	9	4	2	3	1	0	3	0	1	1
Withdraw	17	7	9	3	4	5	18	12	6	5
Survival rate	96.3%	98.2%	99.1%	98.5%	99.5%	100.0%	98.4%	100.0%	99.4%	99.3%
CSR	96.3%	94.6%	93.8%	92.4%	91.9%	91.9%	90.4%	90.4%	89.8%	89.2%
SD (±)	1.3%	1.5%	1.6%	1.8%	1.8%	1.8%	2.0%	2.0%	2.1%	2.2%

b

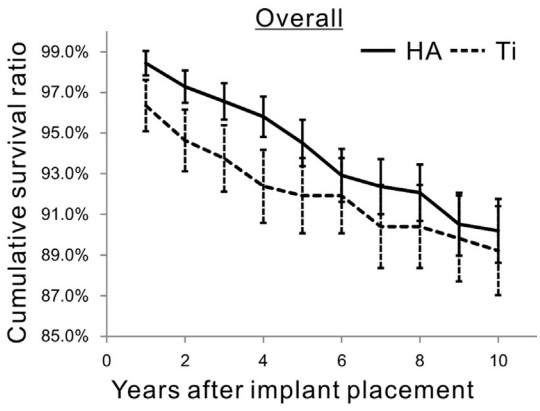

Fig. 4 – List showing the number of failure, withdraw and survival and cumulative survival ratio (CSR) (a) and life table based on overall CSR (b) of nanopolymorphic crystalline HA-coated or anodic oxidized implants in each interval year until 10 years after implant placement.

analysis at the initiation of final-year was 283 and 151 in HA and Ti-implants, respectively. There were no significant differences in CSR between both types of implants at any interval year (Fig. 4b).

CSR of implants at upper and lower molar sites were analyzed as frequent implant locations. CSR in HA implants at upper molar site was 99.4%, 94.6% and 89.9% at 1, 5 and 10 years after implant placement, respectively (Fig. 5a). In contrast, Ti implants at upper molar site showed 90.0%, 77.7% and 77.7% of CSR. CSR at upper molar site was consistently higher in HA-implants than in Ti-implants until 8 years after implant placement ($p < 0.05$, z-test) (Fig. 5a). The values in HA-implants annually reduced and did not significantly different as compared to Ti-implants after 8 years despite even over 90% at 9–10 interval year. At lower molar site, CSR was 97.2%, 94.1% and 89.8% in HA-implants and 98.7%, 96.0% and 94.0% in Ti-implants at a 0–1, 4–5 and 9–10 interval year after implant placement, respectively (Fig. 4b). There were no significant differences in CSR at any interval year between both types of implants at lower molar site. As

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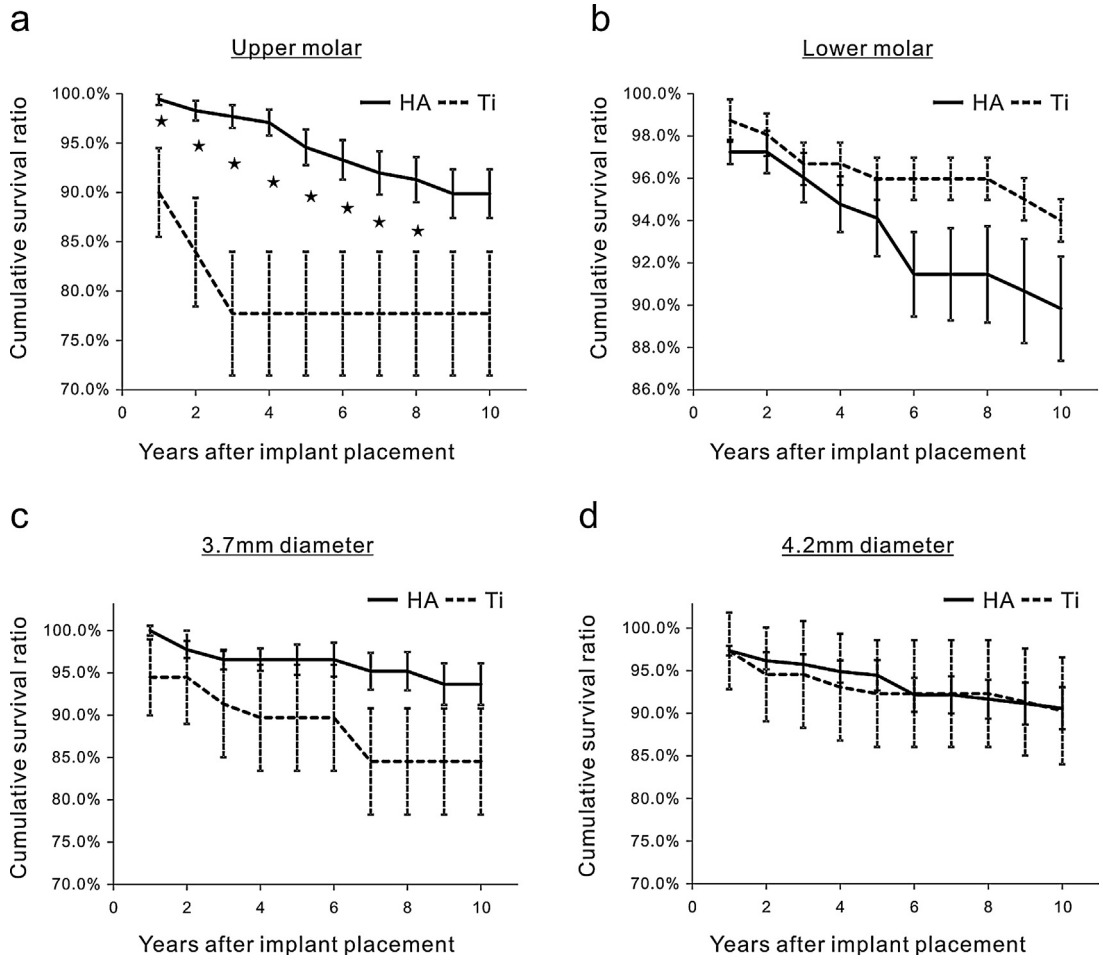

Fig. 5 – Life table based on CSR of nanopolymorphic crystalline HA-coated or anodic oxidized implants in each interval year until 10 years after implant placement corresponding to upper (a) or lower (b) molar site as implant location and 3.7 mm (c) or 4.2 mm (d) as implant diameter. ★$p < 0.05$, significant difference between both types implants at corresponding interval year (z-test).

with lower molar site, there were no significant differences in CSR at any interval year between both types of implants with 3.7 or 4.2 mm diameter (Fig. 4c and d) which were frequent implant diameters.

4. Discussion

Many basic studies suggested that osseointegration capability of implant surface is one of the important factor determining short- and long-term stability of dental implants [26]. Osseointegration capability is histologically expressed the contact ratio of implant surface with matured bone tissue and the volume and quality of surrounding supportive bone tissue [27]. In addition, the amount of collagen, non-collagenous protein and proteoglycan affect adhesive and delamination strengths at bone-implant interface [28,29]. All of those macro- and micro-structures modulate osteogenic cellular behavior on implant surface and determine osseointegration strength [30,31]. In this study, overall CSR value did not show significant difference between both types of implants at any interval year. In contrast, HA-implants placed on upper molar site showed consistently higher in CSR at any interval year than Ti-implants until 8 years after implant placement. Interestingly, there were no significant differences in CSR of implants placed on lower molar site at any interval year between both surface properties. Alveolar bone on upper molar site is often softer and more difficult for initial implant fixation than that on lower molar site, but then again, known to be abundant in cellular component required for osseointegration [32]. Therefore, osseointegration capability of implant surface is more important on upper molar site than on lower one. These indicated that this type of HA-coating substantially enhanced osseointegration strength under clinical situation as compared to anodic oxidized Ti-surface, and more importantly, the efficacy was not only transitory phenomenon until acquirement of osseointegration, but also continued to influence the clinical stability over 5 years.

Retrospective observation study inherently contained many biases; that was applied for this study universally. As distribution of implantation sites, HA-implants trended to be placed at upper molar site, whereas, Ti-implants were at lower molar site. These resulted from consideration for the implant surface potential with bone quality at implantation site in

mind. In facts, HA implants were higher in frequency of bone quality 4 in Lekholm and Zarb classification than Ti-implants. HA implants might acquire faster and stronger osseointegration than that around Ti implants, but the implant surface might lose the needle-like nano-structure during or after osseointegration by chemical dissolution or bone remodeling and the titanium substrate was exposed over many years. Interestingly, the CSR value at molar site supported the clinical consideration for implant surface property. However, there were no significant differences in distribution of sex and in an average age between both types of implants. Moreover, there was no difference in distribution of implant length and frequency of bone augmentation; this indicated that the situation of bone volume at implantation site was not different between the both types of implants. The clinical indication criteria for dental implant therapy in the clinic did not include general disease inducing disorder of bone metabolism. In addition, most parts of implant diameter were 4.2 mm and 3.7 mm in the both types of implants in this study. There was significant difference in CSR regarding neither diameter between the both types of implants. These indicated that bone metabolism of patients included in this study might to be fair or disadvantageous for HA-implants in the comparison between both types of implant surface.

The most frequently used prosthetic design in patient group included in this retrospective study was the single crown, which was followed by fixed partial and full-arch prosthesis. Removable prosthetic appliance was used rarely. Types of prosthetic designs were not subjected to data analysis because this study focused on difference in long-term clinical outcomes between the same implant systems with different types of surface property and because the number was judged to be not enough for statistical analysis. Correlations between surface property, prosthodontic design and long-term clinical outcome were of great interest for future analysis after more accumulation of clinical data.

Theoretical explanation for acquirement of short-term clinical stability of this HA implant can be drawn based on the previous basic studies. The biological and physicochemical performances of this type of HA-coated and anodic oxidized implants for acquirement and stability of osseointegration were well described in the previous animal studies [21,33]. Biomechanical strength on cylindrical implants with the same HA surface was 1.8 times higher than on titanium implants with conventional sandblasted surface alone in rat femur model [21]. Over 90% of bone-implant contact ratio (BIC) with little soft tissue intervention was observed on the HA implants in contrast with approximately 40% BIC and soft tissue intervention on sandblasted surface. In contrast, titanium implants with the same anodic oxidization on sandblasted surface increased neither BIC nor biomechanical strength as compared to sandblasted surface alone in the same experimental model despite slight enhancement in mineralization in bone-implant interface at early healing stage [33]. This HA-coating was carried out with flame spray and low-temperature calcination method which provides a drastic alteration in surface morphology on sandblasted titanium substrate as shown in Fig. 1. Atomic force microscopic analysis revealed that this nanopolymorphic crystalline HA-coating increased by approximately two times in surface area as compared to sandblasted surface alone despite difficulty in evaluation based on surface roughness parameter [21]. Expanded surface area increased protein deposition to help osteoblastic cellular attachment on surface [34] and nanotopography itself enables to modulate cellular function via intracellular changes induced by force and chemical signaling through focal adhesion plaque [35]. Such nano-structure in combination with micro-roughened titanium substrate has a potential to enhance osteoblastic behavior on surface leading to upgrade of osseointegration [23,36].

In addition to nanotopographic feature, the HA implants might simultaneously change surface physicochemical property for enhancement of osseointegration when compared to sandblasted titanium surfaces. HA has both negative and positive electric charges at P and Ca sites in column and therefore can trap electrically polarized molecule including protein [37]. Proportion of Ca ions to P ions in constitutional formula of HAs for this implant was 1.66 [21], which was close to a stoichiometric HA. It is generally known that a stoichiometric HA hardly undergoes chemical dissolution by blood and tissue fluids [38] during osseointegration due to its chemical stability. Chemical solubility of this type HA implant was denied in previous animal study using rat femur [21]. It can be speculated from these information that this type of HA implant did not scatter Ca ions to local environment, which promotes osteoblastic cellular function at moderate concentration but induces apoptosis at over-concentration [39]. Determination of physicochemical property of this type of HA-coated surface will be of great interest for future basic research.

The CSR in HA implants was higher than the Ti-implants at upper molar site consistently for 8 years after implant placement but showed gradual reduction. In addition, higher CSR in HA implants was observed only on upper molar site but not on lower molar site. It was difficult to explain this site-specificity of long-term clinical performance of the HA implants. One assumption might be drawn based on the basic knowledge about surface property of this HA implant. Previous animal study using rat femur demonstrated that binding strength was higher at bone-implant interface than at interface between HA-coating and titanium substrate in both cortical and bone marrow regions [21]. This implied that accumulate fatigue by functional loading was likely concentrated on at interface between HA-coating and titanium substrate rather than bone-implant interface. Release of micro- and nano-particles of HA into local environment induced inflammation [40]. Lower molar site is obviously harder in bone tissue and susceptible to external force other than occlusal loading such as tongue or masticatory muscles, than upper molar site.

As background at the beginning of the 1990s, implant's micro- and macro-design had been changing from the first generation implant characterized by one-piece or external connection implants with machined, TPS or plasma-sprayed HA surface to the second generation implants such as internal connection implants with roughened surface at micron to submicron level. Hence, the selection of different types of implant was groped for each case. There was significant difference in distribution of number of implant placement according to year between the types of implants. Ti-implants

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surveyed in this study were launched in 1992 and HA-implants were in 1996 by the same company. This difference may result from the difference in the timing of the sellout and clinical judgments based upon the basic knowledge about implant surface property. On another front, practitioner's development in clinical skill and knowledge for implant therapy was not neglected for interpretation of the outcome because this retrospective study was carried out at single-center by single practitioner who had eventually become an implant specialist certified by Japanese Society of Oral Implantology. It was undeniable that multivariate analysis should be ideally required to prove causal association between implant property and long-term clinical outcome in retrospective study. However, the clinical outcome obtained in this study should be of interest in the light of direct comparison for 10 years between the different types of implant surface originated from the same system and provide important information for many practitioners in implant therapy to select type of implant surface for long-term prognosis of dental implant therapy.

5. Conclusions

Under limitation of this retrospective study, the nanopolymorphic crystalline HA-coated implants were more survived at upper molar site than anodic oxidized implants until 8 years after placement.

Conflicts of interest

All authors have no conflicts of interest.

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