Chapter 2 Features of the AQB implant system

AQB Implant Team of Development and Clinical Research

I. Stability and safety of the AQB implant in vivo

The biggest advantage of the AQB implant is its one-piece structure, and yet it has long-term stability in the body. Results of clinical trials show its treatment success rate to be roughly 95%, and it is highly reliable [1), 2)]. Properties that support its success in trials are the processing of the implant surface, and technical advances that represent application of the vast number of research results that have been accumulated that concern interactions with bone, and interactions with the gingivae.

The two-piece type and T-type, both of which were placed on the market later, have also adopted the advantages of the system, and supported the concept of the one-piece type. The research and analysis of the products of other companies have also been taken into consideration in order to improve the stability and safety. Its outstanding features are described in the following chapter.

II. The features of surface treatment of the AQB implant

A. Re-crystallized hydroxyapatite

The methods of dental implant coating has been researched and applied over the years. Apart from hydroxyapatite, the raw materials used for coating include calcium phosphate ceramics and titanium. The main objectives of coating techniques are to enable rapid adhesion to bone. The most common method used is plasma spraying (Fig. 4-2-1). The plasma spray method uses a high-temperature plasma flame (around 10,000°C) where the powered material is introduced into the plasma jet, and is propelled onto the implant (titanium) surface. The speed of emission is greater than the speed of sound, resulting in the formation of a film that is strongly adsorbed onto the substrate.

Previous hydroxyapatite-coated implants were sold straight after coating with the plasma spray method. The decline in temperature, from the high temperatures used to melt calcium phosphate to room temperature, readily resulted in the formation of by-products. A coating layer made this way has calcium oxide (CaO) or tetracalcium phosphate (TeCP) incorporated in addition to the main hydroxyapatite ingredient, which mostly consists of amorphous hydroxyapatite. The outstanding biocompatibility of hydroxyapatite is only applicable to the pure, crystalline form. The impure forms described previously, that include impurities and amorphous forms, dissolve rapidly *in vivo*, weakening the coating layer. This technical dilemma had been the prime reason for the poor worldwide reputation of hydroxyapatite coatings.

However, the outstanding biocompatibility of hydroxyapatite was obvious from the results of animal tests. Therefore, the AQB implant team sought methods that would retain the crystal structure of hydroxyapatite, and discovered re-crystallized hydroxyapatite. We became the first in the world to apply this.

Fig. 4-2-1
Plasma spray

What is re-crystallized hydroxyapatite?

Re-crystallized hydroxyapatite is formed by subjecting tri-calcium phosphate, a type of calcium phosphate that is the same as hydroxyapatite, to hydration reaction. Depending on the crystal type, tri-calcium phosphate can be categorized into a β- and α-type, and the α-type has been known to react with water, forming hydroxyapatite. The AQB implant uses β-type tri-calcium phosphate as the powdered raw material in the plasma spray. The tri-calcium phosphate introduced into the spray flame is applied onto the substrate in a similar manner to the usual plasma spray coating, forming a film. Here, in the high-temperature flame, a phase transition occur s from β-tri-calcium phosphate to β-tri-calcium phosphate. The coated layer on the substrate surface is therefore an "α-tri-calcium phosphate coating".

Since the temperature of the flame does not change in changing the raw material to tri-calcium phosphate, by-products are still deposited at the time of film formation (as with the hydroxyapatite coating of the past). Even though the melting temperature of tri-calcium phosphate is higher than that of hydroxyapatite and it is more difficult to form by-products, yet production of these cannot be avoided. In the AQB implant, a specialized technique has been developed to convert the α-tri-calcium phosphate coating into a hydroxyapatite coating, under specific conditions. During this process, the by-products are melted and dispersed in the atmosphere, then the dispersed by-products recycled and become incorporated as a part of the pure crystalline hydroxyapatite crystals (Fig. 4-2-2).

The re-crystallized hydroxyapatite coating consists of a crystal body with a purity of >95%, close to that of a sintered compact, and therefore including only a minute amount of by-products (Fig. 4-2-3-a,b). The surface coating is covered with exposed, highly pure hydroxyapatite microcrystals (Fig. 4-2-4 a,b). Their high biocompatibility was proven in both cell culture experiments (Fig. 4-2-5, 4-2-6) and animal testing (Fig. 4-2-7). These results therefore suggest that this process has overcome the disappointments encountered with previous hydroxyapatite-coated implants.

This re-crystallized hydroxyapatite coating enables the AQB implant to fuse with bone. A cylindrical implant with a diameter of 4 mm, coated with re-crystallized hydroxyapatite, and a non-coated titanium implant were inserted into the femur of a dog, and the reactions of the surrounding tissues and force required to pull these out of the bone were compared (Fig. 4-2-8-a,b). The implant with the re-crystallized hydroxyapatite coating showed active cell differentiation at implantation, and by three months, mature bone was found to surround the implant structure, which was not observed with the non-coated implant.

Fig. 4-2-2
Manufacturing process of recrystallized hydroxyapatite

Hydroxyapatite ($Ca_{10}(PO_4)_6(OH)_2$) is a type of the calcium phosphate that is the main constituent of the bone and teeth, therefore has a high biocompatibility with the biological tissues, and has the ability to bond with the biological bone with given time. The coating technology in the past was still insufficient to allow even coating without the impurity contents therefore often preventing interaction to be formed between the implant and the structures in the body. The development of AQB implant was conducted with the aim to obtain sufficient stability deriving at the final implant that was coated with recrystallized HA. This has been produced using tri-calcium phosphate (TCP, $Ca_3(PO_4)_2$) that is relatively resistant to high temperatures and show osteoinduction, which was applied to the implant body with the plasma spray method into a thin coating layer, which was subsequently converted into the recrystallized HA by a treatment to achieve high biocompatibility for gingival attachment (Japan patent no. 3198125).

a) b)

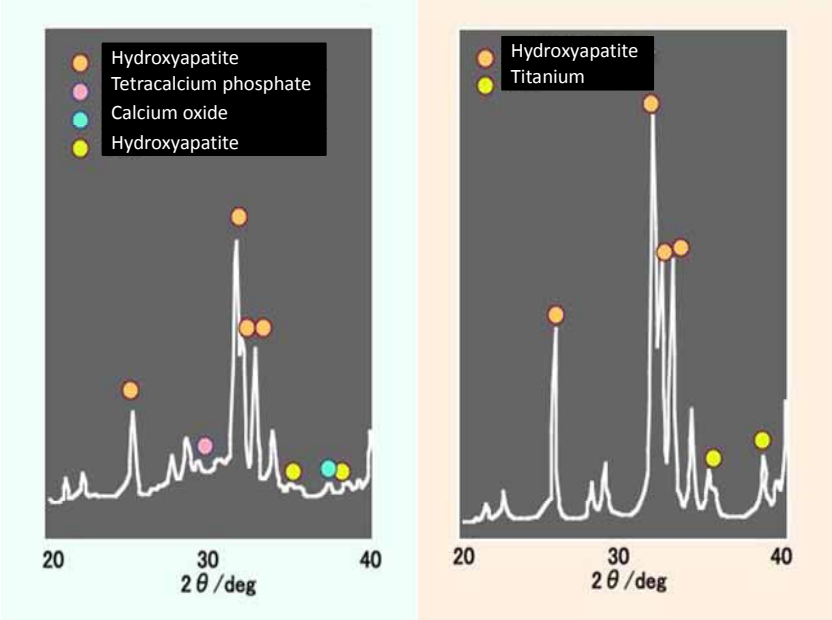


Fig. 4-2-3-a,b

a) The X-ray diffraction data of coating layer sprayed with HA

b) The X-ray diffraction data of coating layer after undergoing the process for recrystallized HA

To derive at a highly crystalline HA, several factors need to be considered: the plasma frame, spraying distance, spraying speed, and the size of the raw materials. The resulting HA layer, coated with the past manufacturing methods using HA powder as the raw material, included impurities with high pH such as Calcium tetraphoshate (TeCP) and calcium oxide (CaO) (Fig. 4-2-3-a). TeCP and CaO both are highly soluble therefore are thought to be the reason for the vulnerability of the HA coating layer. In contrary, the purity of the recrystallized HA layer can be observed to be high from the X-ray diffraction analysis.

a) b)

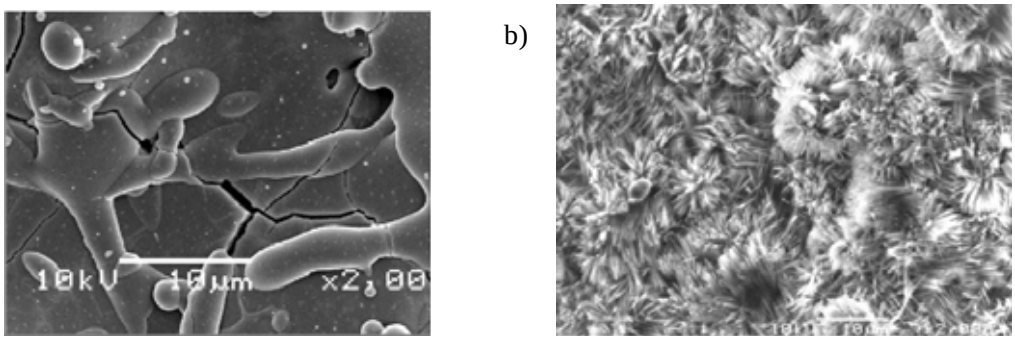


Fig. 4-2-4

a) The coating layer sprayed with hydroxyapatite.

The rapid cooling from the high temperatures of the plasma spray results in decomposed and dissolved coating on the substrate that appears as a vitrified state. Strong alkaline agents such as CaO are yielded as the by-product, resulting in low crystalline, low purity product.

b) The coating layer of recrystallized hydroxyapatite

The surface is covered with needle-like hexagonal microcrystals of highly pure HA. The coating layer of 35 µm is difficult to peel off. The layer is made up of HA, without presence of any decomposition product from the high temperatures, and is highly crystalline. In immersion experiments, no changes in the pH of biological saline that was used as the solvent could be detected, and its solubility has been shown to be low in both *in vivo* and *in vitro*.

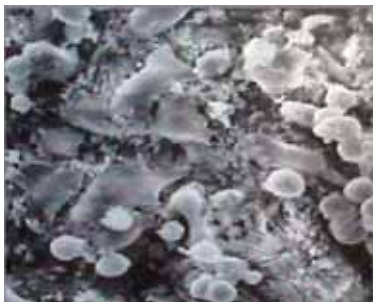


Fig. 4-2-5

An image of human healthy osteoblasts planted on AQB implant, taken with scanning electron microscope (SEM) – the typical circular shape in some of the cells can be seen, but much of the others show an elongated shape to stabilize and to adsorbed onto the surface *in vivo* (after 2 hour incubation period).

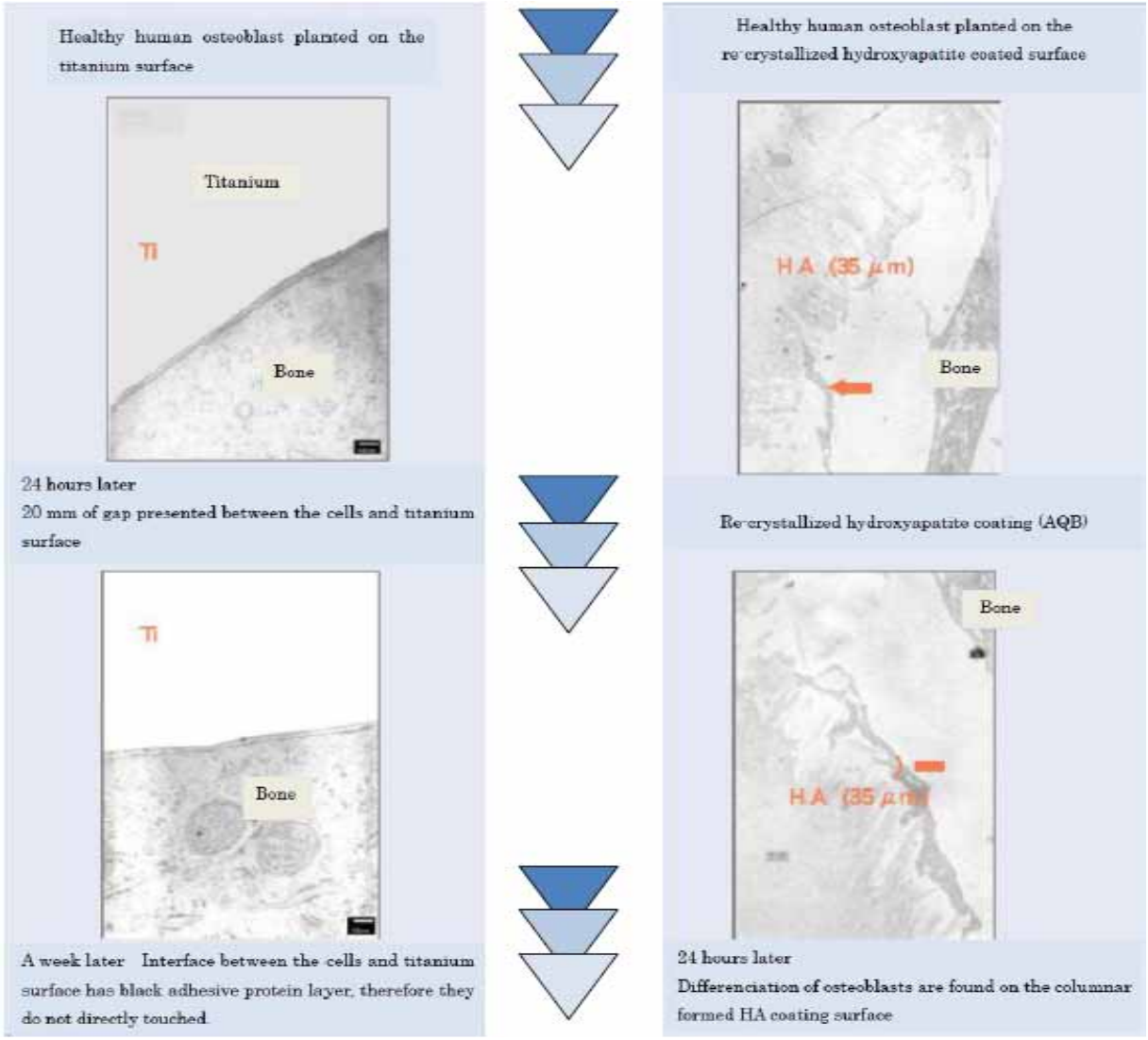


Fig. 4-2-6

Healthy human osteoblast planted on the re-crystallized hydroxyapatite (HA) coated surface and titanium surface. Transmission electron microscope (TEM) was used to analyze the interface between the material surface and the cells.

An accelerated differentiation of osteoblasts was observed on the surface of re-crystallized HA coating even at 24 hours, whereas the 20 mm gap at the interface between the cells could still be visible with those planted on the titanium. There were no changes to be seen even after one week. These images indicated that the differentiation of osteoblasts have been promoted on the surface of rexrystallized HA. (Taken from Abstracts for the seventh IAI Clinical Research Presentation)

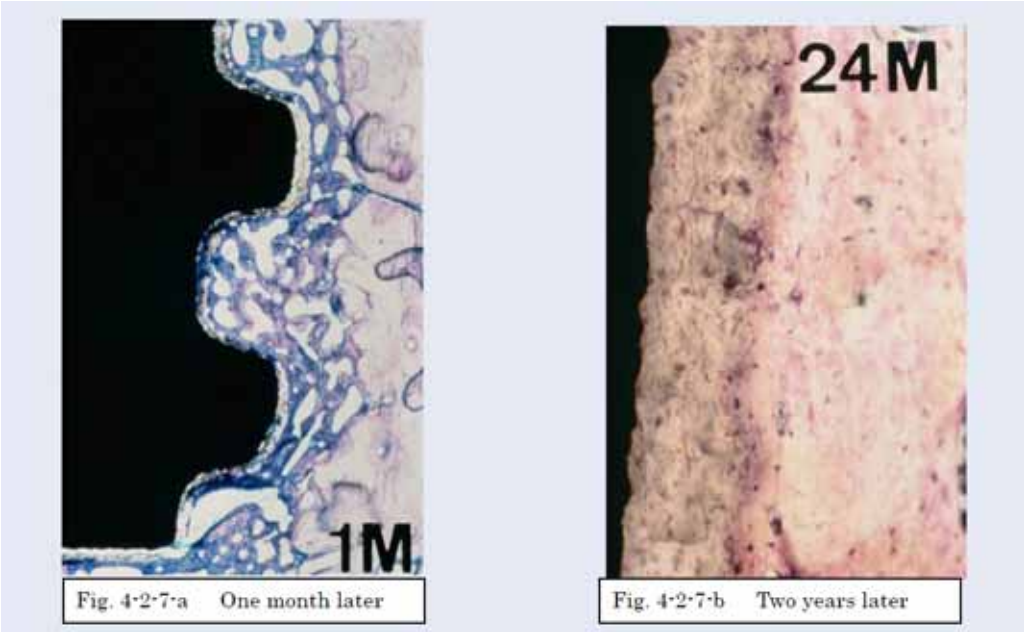


Fig. 4-2-7 a, b

The re-crystallized HA coated titanium was inserted into an animal bone, and the progress was monitored with optical microscope. After a month, the coating layer had already become covered with newly generated bone (a. newly generated bone is shown in blue), and, a strong interaction can be seen after 2 years (b). The high biocompatibility of recrystallized HA is evident from this data.

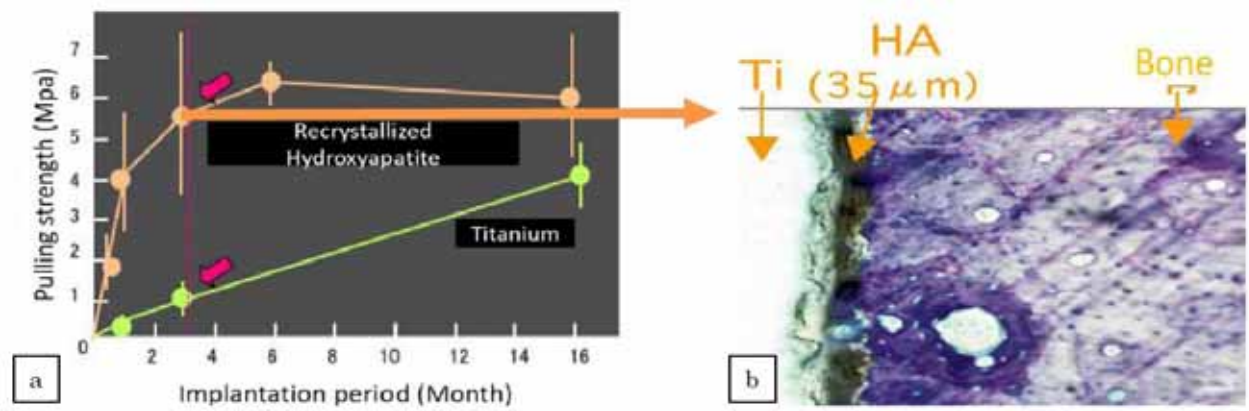


Fig. 4-2-8-a

The relationship between the pull-out strength of the bone and the duration of the implantation of re-crystallized HA coated material

Fig. 4-2-8-b

The interface between the surfaces of re-crystallized HA coat and the bone, after 3 months (Toluidine blue stain)

The HA coated material required 4.1 MPa after a month, and 6.3 MPa after 6 months of implantation for the bone to separate, thus suggesting rapid interaction to be formed with the bone. Meanwhile, the titanium-only material was able to be pulled out with 0.4 MPa after a month. A gradual increase in the strength required to pull out the titanium implant could be observed, but the maximum strength was 3.6 MPa even after 16 months, the equal amount of strength required after a month with the re-crystallized HA coated material. This data suggested that the recrystallized HA coat to have the ability to rapidly interact with the bone, with a sealing property that prevents the microorganisms from entering the body.

B. Surface treatment of pure titanium to improve its biocompatibility

In contrast to the field of orthopedics, the dental implant can be said to be under severe conditions, as it is subjected to the risk of contracting infection from the time of insertion. Infection in implants, which is prevalent at the initial stages of implantation due to movement within the socket, can be decreased with the two-piece type, as the fixture is completely enclosed within the gingiva. However, as the majority of AQB implants are of the one-piece type, the post-surgical state involves penetration of the bone and the gingiva by the implant structure. The incidence of peri-implantitis with the AQB one-piece type was surprisingly no greater than with other implant types, and was associated with a good prognosis. The re-crystallized HA coating, with its rapid integration with the bone, decreased the incidence of bacterial infection.

Another factor is the mirror polishing of the pure titanium surface. Usually, the titanium surface is covered by an oxide layer that is roughly 4 nm thick. Even if the surface is treated with acid to remove this layer, another oxidized layer re-forms instantaneously on the titanium surface on exposure to air. This oxidizing property inhibits the leaking of toxic metal ions into the blood circulation in vivo, indicating the safety of titanium in the body.

In the AQB implant, the thickness of this oxide layer is increased by immersing it in a solution containing calcium and phosphate, for a long period of time. This treatment increases the thickness of the mirror polished part of the layer to 8 nm (Fig. 4-2-9-a, b, c). This oxide layer is much thicker than that of the pure titanium, thus improving the safety in vivo; it also incorporates more phosphate and calcium from the solution, thereby providing increased biocompatibility (Fig. 4-2-10 a,b, Table 4-2-10a,b). The cell amplification assay with fibroblasts also showed significant affinity, in comparison with the usual titanium material, therefore sufficient gingival closure can be expected (Table 4-2-1-a, b, c).

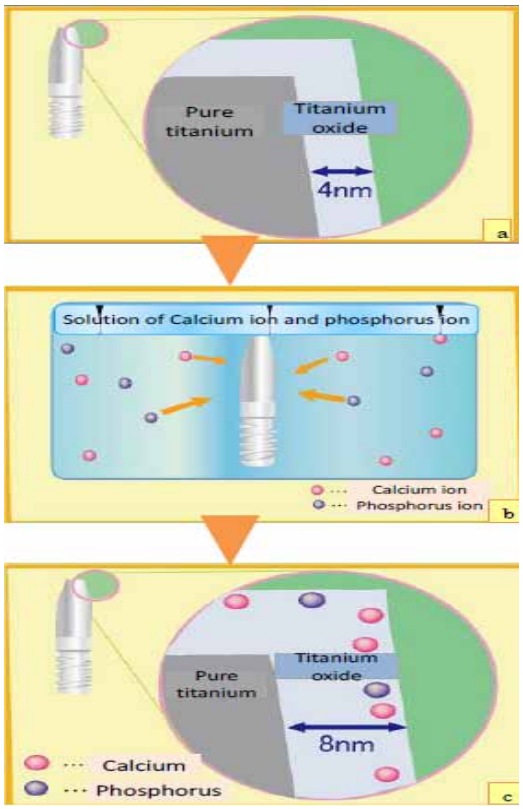


Fig. 4-2-9

a) Before treatment

The titanium surface is usually covered with a thin oxide layer (4 nm).

b) Treatment for increasing biocompatibility to improve gingival attachment

Immersion of AQB implant in a solution containing calcium ions and phosphate ions. The oxidation process of the titanium surface is accelerated by this treatment and with simultaneous incorporation of calcium and phosphate.

c) Post-treatment

The thickness of the oxide layer is increased from 4 to 8 nm with the treatment. Calcium and phosphate ions become more concentrated close to the surface of the oxide layer, therefore increased biocompatibility with the gum.

	Concentration ratio (%)			
	Ti	O	Ca	P
Pure water polishing Ti	27.0 (0.6)	73.0 (0.5)	-	-
Treatment for increasing biocompatibility to improve gingival attachment Ti	26.5 (0.6)	72.2 (0.2)	3.2 (0.1)	1.1 (0.3)

Table 4-2-1-a

The contents of surface titanium oxide with the treatment for increasing biocompatibility to improve gingival attachment

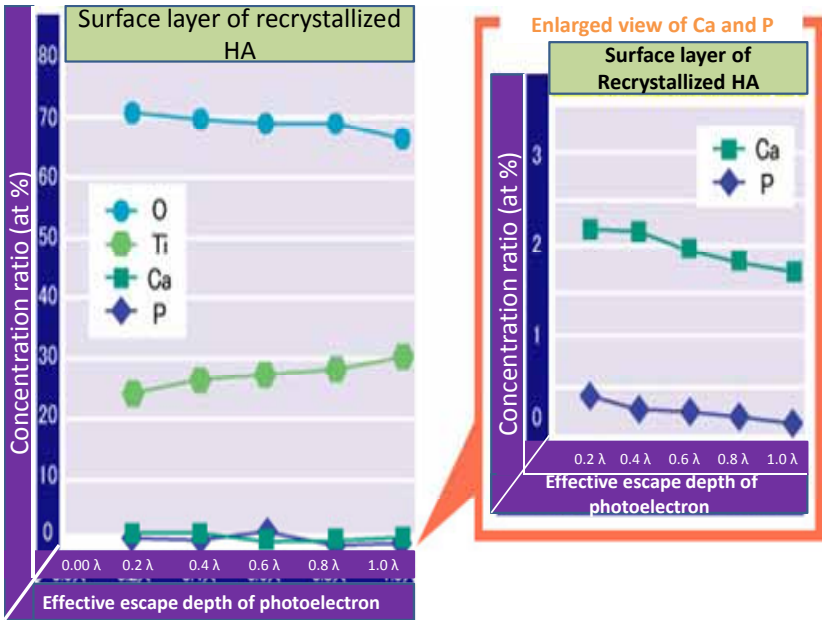


Fig. 4-2-10-a

The concentration distribution of the titanium surface after the treatment for increasing biocompatibility to improve gingival attachment

Treatment	$[OH^-]/[O^{2-}]$	$[Ti^{4+}]/[Ti^{2+}]+[Ti^{3+}]+[Ti^{4+}]$
Pure water polishing Ti	0.522	0.080
After the treatment of High biocompatibility for gingival attachment	0.432 $[OH^-]$ Decrease ↓	0.966 $[Ti^{4+}]$ Increase ↑

Table 4-2-1-b

The change in the concentration ratio of OH^- and Ti^{4+} ions with the treatment for increasing biocompatibility to improve gingival attachment. The oxidation and dehydration is occurring on the titanium oxide surface layer.

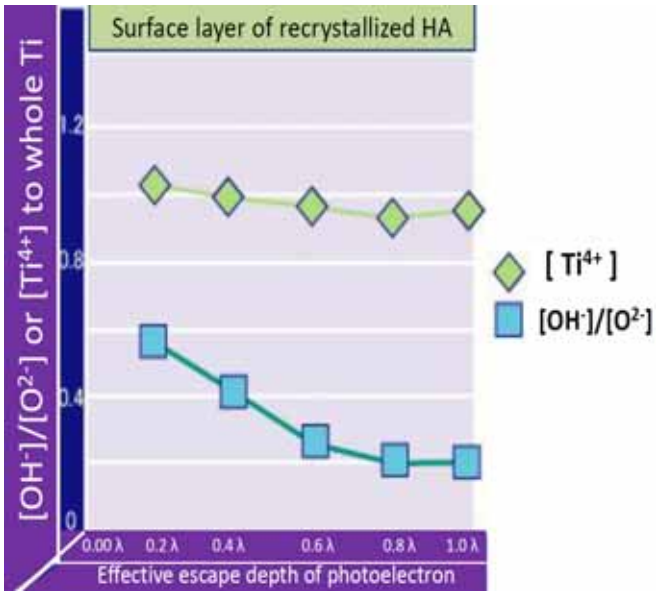


Fig. 4-2-10-b

The change in the concentration ratio of OH^- and Ti^{4+} ions in the titanium surface oxide layer after undergoing the treatment for increasing biocompatibility to improve gingival attachment. More oxidation can be observed at the surface.

[Analysis of the surface structure of AQB implant fixture using X-ray photoelectron spectroscopy (XPS)]

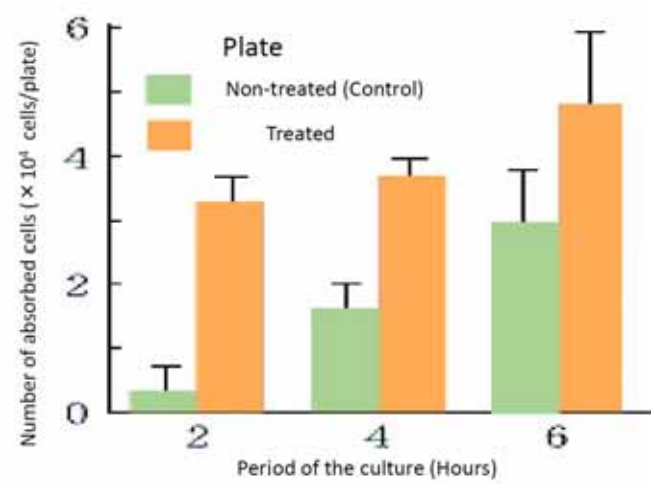
Experimental

Pure titanium plate (10×10×1 mm) was mirror polished, washed with acetone using ultrasound, treatment for increasing biocompatibility to improve gingival attachment, cooled to room temperature, washed with de-ionized water and sterilized in autoclave, before the analysis with XPS.

Results and observation

The ratio of oxygen on the surface was higher after undergoing the treatment for increasing biocompatibility to improve gingival attachment than those without. After, this treatment, the Ca and P were detected (Ca was present in abundance on the surface, whereas only a scarce amount of P was detected) (Table 4-2-1-a, Fig. 4-2-10-a). The thickness of the layer increased from 4 nm to 8 nm (Table 4-2-1-b). The OH^- group on the oxide layer decreased after the treatment, while Ti^{4+} showed an increase, suggesting progress of dehydration and oxidation (Table 4-2-1-b, Fig. 4-2-10-b)

a)



b)

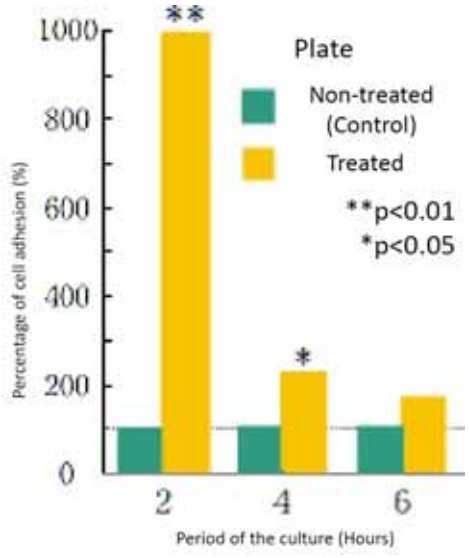


Fig. 4-2-11-a

a) The change in number of attached cells with time

b) The change in the ratio of attached cells (reference: 100 %)

The fixture of AQB implant is first mirror polished, followed by the treatment for increasing biocompatibility to improve gingival attachment. The sealing ability was compared between the cell culture that had been treated with one that was only mirror polished without the subsequent hydrothermal treatment step.

Experimental method

The titanium plate (10 mm) was immersed in culture solution before culture cell (1×10^5) was spread evenly on its surface, and left incubating for 2 hrs, 4hrs and 6hrs to be left adsorbed. After washing the cells, the number was calculated using neutral red uptake method. As the replacement of the gingival fibroblast, human normal skin fibroblast (NB1-RGB cells, Riken Genebank) was used as the cultured cell.

Results and observation

The sowing of the cells were faster on the surface that had undergone secondary treatment (AQB), compared to the non-treated, and amplification and its stability were observed (Fig. 4-2-11-a). Setting the control (untreated) value to be 100 %, the fraction of the adsorbed cells were found to be higher with shorter time period of the culture, at 2 and 4 hours, the fractions were 10 times, and twice of the control, respectively. After 6 hours, only marginal differences were observed (Fig. 4-2-11-b). These results suggested that the surface material of the fixture had excellent initial adhesive abilities to fibroblasts.

III. Design features of the AQB implant

A. Spiral cylinder form (Fig. 4-2-12)

Dental implants are broadly classed into screw-type and cylinder-type implants, depending on the structural form of the portion buried within the jaw bone. The screw-type is the main type adopted in the non-coating implants, and is self-tapped to establish primary stability. The self-tapping method is where the hole is drilled smaller than the diameter of the screw groove, and the implant is delved deeper into the hole with the use of the screw ridges to stabilize the implant. The residual stress to which the bone is

subjected is the main concern with this type. The cylinder type, on the other hand is a simple pillar shape, and is stabilized in the bone by forcibly pressing it in. HA-coated implants often are in this form. The hole in which it is buried has the same diameter as the cylinder, therefore, the bone is subjected to less stress, but because the fixing force is gained by the frictional resistance, the primary stability of this type is less than those with the self-tapping method.

The AQB implant is classed as cylinder type due to its shape. In the AQB implant, the ridge of the screw is of a flat, threaded type with a trapezoidal screw, and the implant body is rotated to achieve settlement at insertion. The insertion hole is initially drilled to have a diameter that is the same as the external diameter of the trapezoidal screw, therefore, it has no tapping effect. In this case, initial fixation is only due to friction resistance between the ridge of the trapezoidal screw and the non-screw part of the fixture. The AQB implant limits the damage to bone to a minimum, and interacts with and fits into the bone by virtue of its excellent ability to adhere to bone. The bone adhesion is largely due to the re-crystallized HA coating. Because the insertion hole is set to be the same size as the screw ridge, a gap between the screw groove and the ridge exists at the time of implantation. This gap is filled up with blood, fractured pieces of bone, and cancellous bone that result from the rotating and inserting motions of the screw. These inclusions are beneficial for bone formation, and with the aid of the bone-inducing properties of the re-crystallized HA, neonatal bone is developed.

Fig. 4-2-12
The screw for the AQB implant has employed the trapezoid screw with a flat screw thread

B. Applying the “SOL form” to the interdigitations of the two-piece type

Typical interdigitations used in two-piece types are either hexagonal or octagonal. Hexagonal (HEX) can be fitted in six different ways, and is resistant to rotational stress. However, depending on the angle of insertion, lateral force acts at the corners, causing breakage. Other interdigitation types include tapered structures. Tapered structures have no corners, and thus have a high stress-distributing ability. However, the difficulty lies in the fact that the direction of abutment placement has to be remembered, and resistance to rotational stress is lower than with the hexagonal structure.

A unique structure was developed for the AQB two-piece type implant in order to eliminate the properties that made previous two-piece implants vulnerable. The corners of the hexagon were removed, and the two pieces were joined with the use of smooth curves to form a unique interdigitation, called the “SOL system”. SOL stands for Smooth Octagonal Lock. By erasing the corners, the concentrated stress that was exerted on the hexagonal structure was no longer present, thereby reducing the incidence of breakage. Eight different angles of interdigitation are now present, and therefore slight adjustments to the angle of attachment to the abutment are possible. Regarding rotational stress, sufficient resistance is present, and there is thus improved stability in comparison to the tapered type.

The only problem that may be caused by this approach is that in a similar manner to the tapered type, the high degree of freedom present with the octagonal shape means that the direction of attachment to the abutment can be lost in the oral cavity. In such case, it is recommended to construct an apparatus that indicates the direction of the interdigitation.

Fig. 4-2-13
The original interdigitation, “SOL system” for AQB two-piece type implant

C. The internal joint of the fixture and abutment (Fig. 4-Two-14)

The attachment of the fixture and abutment uses an internal joint, fixed with screws composed of titanium alloy. The junction between the fixture and abutment are sculpted with an ultra-precision cutting technique. Scanning electron microscopy (Fig. 4-2-15) has confirmed that the accuracy of the fit is good.

IV. Mutual use of abutments

The abutment of the AQB two-piece type is constructed with a fitting that is universal for fixture of any size. In many other implant systems, several abutments are available for each of the fixture sizes in their lineup, as the abutment diameter is dictated by the size of the fixture. For example, 15° angled abutment for a 4 mm diameter fixture, as well as 15° angled abutment for a 5 mm diameter fixture.

There are instances where at the time of choosing the abutment, the straight type was deemed appropriete, however, the use of angled type was more fitting in the oral cavity or at the stage of modeling. With this universal style of AQB abutment, it is possible to switch freely from the straight type to the other regardless of the diameter of the fixture. It is important to note, if the same abutment is attached to a fixture of a different diameter (4 mm or 5mm), the total length (of the fixture and abutment) can differ by around 0.5 mm. The superstructure of the abutment gives 5° of taper to both the straight type and the angle type, and the shoulder provides a heavy chamfer. This form is also a recommended design in the manufacture of full ceramic crowns using CAD/CAM. By integrating the latest CAD/CAM system, design and manufacture that uses the least amount of material will be possible in the future.

The sizes, SS, S, M, L; or WS, WM and WL (in which the diameter interacting with the gingivae is wider) are included in the product lineup. The distinction between these lies in the length of the gingival interaction that is chosen, depending on the thickness of the gingivae. Otherwise, the design of the implant types is all the same. The angled abutments accommodate two different types (15° and 25°), which are used in regions such as the front teeth or in areas where the installation socket requires parallel adjustment.

Fig. 4-2-14
The connection between the fixture and abutment has employed internal joint

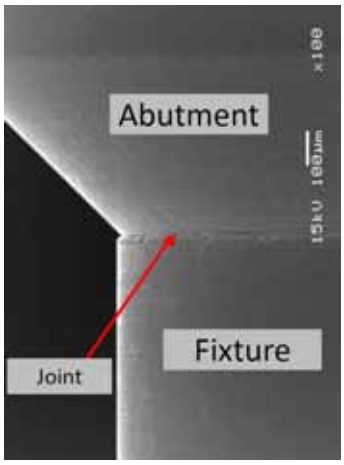


Fig. 4-2-15
Electron micrograph of the AQB implant joint, featuring the high precision in the fitting

V. Mutual use of tools

The tools used (Fig. 4-2-16) for one- and two-piece types, as well as the T-type, are designed so that they can be used for all types. In particular, the drill for hole creation is the same for all three. This has been possible because the diameters of all the parts inserted into the gingiva are designed to be of the same size. In other implant systems manufactured by other companies, even if the implants are from the same organization, use of different tools is often required for each implant type. The AQB system has minimized the number of tools that are specific for each type, therefore, simplifying the surgical operation, widening the options for each patient, and meeting their needs.
A color-coded system is used in the tool box for each of the different types.

Fig. 4-2-16
The surgical tools for the implantation are common for all AQB implant types, one-piece, two-piece and T-type. This is another advantage of this implant system.

VI. Characteristic diagram of the T-type implant

The T-type was developed to overcome the common problems that were encountered with the one-piece type. The one-piece type is characterized by a straight fixture, which had resulted in the following issues: its finished appearance and sinking into cortical bone. The superstructure could not be fitted that resulted in a natural eruption from the tooth cervix. The application of a two-piece type would solve this, but in terms of the cost, time and effort required for surgery, there were cases where a one-piece type would have been more suitable.
The development of the T-type was able to overcome these issues. The T-type is designed with a taper that starts from the end of the HA-coating and with a fixture diameter that is 0.4 mm wider than that of the screw tip. By widening the fixture, it became possible to fit a superstructure with a more natural outlook than was the case with the straight, one-piece type. Secondly, this widening of the fixture part helped to

prevent the implant from sinking further into the bone. The straight one-piece type carried the risk of delving further into the bone on accidental application of external pressure (such as pressure from strong biting) at the initial stages of implantation. In particular, in situations where the implant body protrudes into the maxillary sinus due to sinus-lift procedures, or encroaches on the mandibular canal, the subsidence of the implant further into the bone could result in a serious complication. The widening of the fixture of the T- type acted as an effective wedge in the cortical bone, preventing these problems.

The only precaution that has to be considered when handling the T-type is that accuracy is required when drilling a hole for implantation. With the straight one-piece type, even if the coating is left uncovered, it can still be buried deeper but with the T-type, it may be necessary to remove the implant for careful secondary drilling, to deepen the hole, since the taper will inhibit further insertion into the bone.

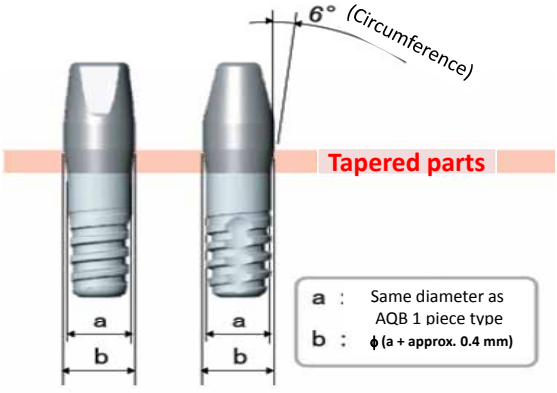


Fig. 4-2-17

The T-type is tapered from the terminal surface of the coating layer, and the diameter of the abutment is 0.4 mm more than that of the screw head.

References

1) Takarada H, Kinebuchi T. Clinical evaluation of hydroxyapatite-coated titanium artificial tooth root. The journal of the Stomatological Society, Japan. Separate volume. 1993; 60(4).

2) Chiba H, Katsuyama N, Kobayashi R, Mishiro F, Uchida M, Kamezawa H, Otani K, Kiuchi T, Hara S, Clinical evaluation of hydroxyapatite-coated 1-piece implants (AQB Implant®). Odontology. Reprint. 1994; 81(5).