Part 8 – To obtain long-term success with AQB

Verification of a surgical procedure that is safe, secure, reliable, and that maximizes the properties of AQB

The conference was held at headquarter of Advance Co., Ltd. on June 4, 2009

AQB implants are known for its excellent characteristics, but the ways in which diagnosis, operation and management should be conducted need to be clarified to achieve long-term stability. The four of the authors who contributed long clinical case studies to this book participated in the debate to define these issues to when gathered to mark the publication of this clinical edition.
Dr Tsutsumi, who has been involved with AQB since its developmental stages, acted as the Chairman for this debate.

■Attendances of clinical case conference

Dr. Takao Kinebuchi (Director of Kinebuchi Dental Clinic)
Dr. Yushiro Kuroyama (Director of Kuroyama Oral and Maxillofacial Surgery Clinic)
Dr. Toshiaki Miyazawa (Director of Tokyo Kagawa Dental Clinic)
Dr. Yasuhiko Tsuyama (General Manager of Department of Dentistry, Oral and Maxillofacial Surgery, Mitsui Memorial Hospital)

(Chairman) Dr. Yoshichika Tsutsumi (Director of Medical Clinic at the Ministry of Foreign Affairs Division of Health and Welfare)

Dr. Takao Kinebuchi

• Graduated from Department of Dentistry, Tokyo Medical and Dental University (TMDU), Doctor of Medical Dentistry.
• Former positions include Director of Department of Dentistry, Oral and Maxillofacial Surgery, Mitsui Memorial Hospital and current position.
• Currently Holds the post of a part time instructor at TMDU. Specialist of Japanese Society of Oral and Maxillofacial Surgeons

Dr. Yushirou Kuroyama

· Graduated from Department of Dentistry, The Nippon Dental University
• Graduated from a doctorial course in Graduate School of Medical and Dental Sciences, Tokyo Medical and Dental University, Doctor of Medical Dentistry.
• Former positions include research fellowship (Doctor) of Japan Society for the Promotion of Science and current position

Dr. Toshiaki Miyazawa

· Graduated from Department of Dentistry, Nippon University.
• Former positions include director of Department of Dentistry, Oral and Maxillofacial Surgery, Mitsui Memorial Hospital and current position

Dr. Yasuhiko Tsuyama

· Graduated from Department of Dentistry, Kyusyu University.
• Former positions include an assistant at Department of Oral and Maxillofacial Surgery, Faculty of Medicine, The University of Tokyo and a lecture at Department of Plastic Surgery, Kinki University and current position
• Medical Advisor of Japanese Society of Oral and Maxillofacial Surgeons

Dr. Yoshichika Tsutsumi

· Completed a doctorial course in Graduate School of Medical and Dental Sciences, Tokyo Medical and Dental University, Doctor of Medical Dentistry
• Former positions include a lecture at Institute of Medical Devices Tokyo Medical and Dental University and current position
• Holds the post of a lecture at Section of Orofacial Pain Management, Graduate School, Tokyo Medical and Dental University

The details of AQB development

Its launch in the midst of adverse conditions, backed by its outstanding properties

Tsutsumi: I would like to begin with the history of AQB implant development (Table 1) in before looking at the case studies.

The development of AQB implants began at the Institute of medical and dental engineering, Tokyo Medical and Dental University (TMDU), and ADVANCE Co., Ltd. in 1983.

The dental implants at that time included a string of failures: the blade type; periosteal implants; followed by the introduction of hydroxyapatite (HA) sintered body, Apaceram® by the domestic manufacturer that had problems with its mechanical strength. The excellent osteoinduction of apatite was already known at the time therefore we instigated the research and development of the apatite composite material that excelled in strength and osteoinducing abilities. I, at the time a member of the institute of medical devices, became involved in the development, and so did Dr Kutoyama, who was enrolled at the Graduate School of Tokyo Medical and Dental University.

Kuroyama: I remember we were faced with the issue of coating titanium with highly crystalline HA at the developmental stages. Initially, HA was spray coated onto the titanium as the raw material, but this method resulted in the inclusion of chemical compounds other than HA (i.e. impurities) such as tetracalcium phosphate (TeCP) and calcium oxide (CaO). The impurities cause solubilization of the coating layer. Eventually, the method of using β-TCP as the raw material, to primarily produce α-TCP coating layer to be converted into recrystallized HA with hydrothermal treatment was derived, after trial and error. I can remember the great efforts put into finding this by the members of ADVACE Co., Ltd.

Tsutsumi: The result of this effort is reflected in the idea of "recrystallization" of HA currently applied in AQB. The issues of the presence of impurities were solved, giving rise to patented recrystallized HA coated AQB with a crystallinity that is close to 97%.

Dr Kunebuchi and Dr Miyazawa, while you were working in Mitsui Memorial Hospital, the facility chosen for the clinical trials, what were your impressions of AQB.

Kinebuchi: The surface structure of the AQB HA coating observed under the scanning electron microscope (SEM) was hugely different from other HA implants, it could be described as an 'alive apatite' (Fig. 1).

Fig. 1 Electron micrograph of AQB recrystallized HA

The difference from those HA that are solubilized and lost their functions were extremely obvious in the SEM image, and I did think this could have the potential and was expectant of the properties that the AQB would show in the clinical settings.

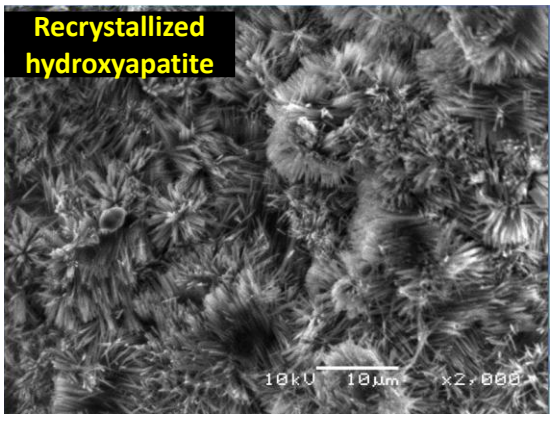

Fig. 1 Electron micrograph of AQB recrystallized HA

Table 1: Detail of developing AQB implant

Year	
1983	● **Started basic research development** (Joint development by the Institute of medical and dental engineering of the Tokyo Medical and Dental University: TMDU, and ADVANCE Co., LTd)
Nov. 1988	● **The first trial was conducted** (Department of Dentistry, Oral and Maxillofacial Surgery, Mitsui Memorial Hospital)
Nov. 1990	● **The second trial was conducted** (Department of Dentistry, Oral and Maxillofacial Surgery, Mitsui Memorial Hospital/ Second Oral Surgery, The Nippon Dental University Hospital)
Dec. 1992	● **Completed clinical trial. Submitted the application for manufacturing approval.**
Jun. 1994	● **Obtained approval from the Ministry of Health and Welfare (Ministry of Health, Labour and Welfare) and launched AQB one piece type**
Aug. 1994	● **Started AQB implant system workshop**
Nov. 1998	● **Started IAI workshop** (Dr. Yasunobu Uchida: first president of IAI and professor emeritus at Tokyo Medical University)
Apr. 2002	● **Launched AQB two piece type implant**
Aug. 2007	● **Launched AQB T type implant**
Jan. 2008	● **Start Japanese society for Advanced Implant Medicine** (Dr. Hiroshige Chiba: president of AIM and head of oral and maxillofacial surgery at TMDU)
Aug. 2008	● **Published basic and clinical of AQB implant**

Miyazawa: I was using implants manufactured by other companies dominated by two-piece type at the time. The fixture and abutment, abutment and superstructure were both fixed with screws, and remember being extremely wearily of its strength and the problems of screw loosening.

Tsutsumi: The secondary trials were started in November 1990 in Mitsui Memorial Hospital and The Nippon Dental University, simultaneously. Thirty clinical examples were collected from the start to the following November and submitted to the Ministry of Welfare (currently the Ministry of Health, Labour and Welfare) (Fig. 2), and was approved. The results were so astonishing that even the officer called us to ask whether the figures were real.

As the evaluation criteria, we adopted the "Effective ratio" established by the Harvard Conference. This standard is known for its strictness, even in comparison to the current survival rate criteria, in that even a minute movement would prevent the implant from being qualified. The AQB scored easily over 90% success rate even with qualification method.

The first workshop was held in August the same year, in which Dr Kuroyama also participated, and this became the start of the AQB action to be in full swing.

Tsuyama: Roughly a dozen or so members took part in the first workshop, and I remember seeing the simplicity of the surgical techniques was like a breath of fresh air.

Fig. 2 Clinical trial documents of AQB

The long-term value of AQB

Recrystallized HA becoming involved in bone regeneration to a downgraded bone

Tsutsumi: The idea of implants at the time of AQB launch were all two-piece, two-stage type, and the body was all made of titanium alone, so it was indeed difficult times for it to be successful.

With the release of an academic article in the U.S. criticizing the gradual solubility of HA over time, the general views in Japan became anti-HA.

Although crystallinity and crystal structures of AQB recrystallized HA are distinct from other HA, without long-term evidence it was difficult to prove its excellent properties. I'm sure the professors in this room pointed this out.

The long-term applications of AQB for over ten years have been presented in this book by the four professors who joined me in the AQB discussion today. I would like each of your views on the long-term outcome of AQB treatment.

Miyazawa: The five cases, all of which have been over ten years since the beginning of their treatments have all shown satisfactory outcome. It is true that at the time when AQB was first launched, there were concerns as to risks of infection, especially because of its one-piece structure, and the skeptical views on the use of HA. The argument that the use of one-piece type is at higher risk of infection than the two-piece type is irrelevant, and in addition, the AQB coating is not just HA that had been applied in the past, but is a recrystallized form that is extremely pure. But the actual clinical results, based on the excellent properties, showed that the primary integration with the bone to be achieved in six to nine months, and the placement of the superstructure to be possible in two months. This concrete evidence helped the clinicians, applying this product, to recognize its clinical efficacy.

Kuroyama: The three cases of AQB one-piece and two-piece type, all have been clinically applied within a short period of time since its release. The typical concern with the long-term clinical examples is the issue of bone resorption occurring at the bone ridge. However, the cases that were presented showed no significant signs of bone resorption for the period of over 14 years. This is thought to indicate the firm interaction between the bone and HA coating layer to be effective in inhibiting the epithelial downgrowth. The seven year study of two-piece type has not shown any signs of loosening of the screw that is holding the fixture and abutment together, and stability in superstructure is evident. The SOL interdigitation system is thought to be contributing to this fact.

Fig 3. “SOL system” original interdigitation form of AQB two-piece type

Tsuyama: The long-term clinical examples that began from the start of the clinical trials in Mitsui Memorial Hospital in 1988 have been followed over the years. The four case studies that were presented in the book are all cases that have been observed for over 17 years. The long-term clinical examples of the professors do not show major bone resorption, and show downgrowth to even recover slightly. Further, the bone surrounding the implant shows more opaqueness than the beginning of the treatment. This can be said to be the property of AQB implants. The excellent properties of AQB in long-term is evident from the 19½-year study of free-end denture with three implants to the mandible (Fig. 4), conducted by Dr Kinubuchi, the longest case study in the history of AQB.

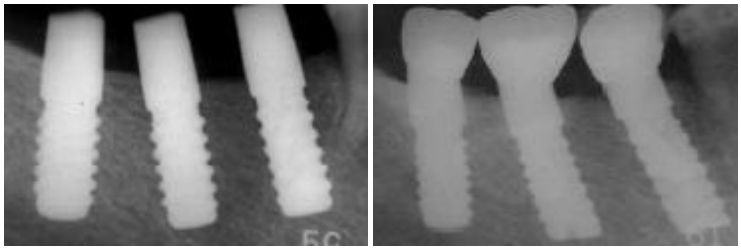

Fig. 4 Dental radiographic appearance of implant: Two weeks after the surgery (Left) and 19½ years after the surgery (Right). No signs of bone resorption was observed even after 19 years. (Picture was presented by Dr. Takao Kinebuchi, Kinebuchi Dental Clinic and Dr. Yasuhiko Tsuyama, Mitsui Memorial Hospital).

Kinubuchi: I agree that recovery of downgrowth does indeed occur as mentioned by Dr Tsuyama. It is unthought-of with general titanium implants. In the book, I described the modification of the bone with time. With biointegrating implant such as AQB, I felt as if the implant structure itself was forming necessary amounts of bone where it was required as an integrated part of the bone. This is purely my own opinion, but were derived from the actual observation and finding similar processes.

Tsutsumi: Dr Kunubuchi has also provided us with the statistical analysis of the cases (Table 2). The 97.3% survival rate after the superstructure placement is incredible.

Table 2 : Survival rate of AQB implant (Totalized case of Dr. Kinebuchi)

■**Installing time, number of people and implants**

At Mitsui Memorial Hospital	March 1,1998 – November 28, 1996	70 people	193 implants
At Kinebuchi Dental Clinic	February 25, 1997– June 16, 2007	411 people	1,306 implants
Total		481 people	1,499 implants

■**Removal cases (Fall out)**

Removal case including before and after placing prosthesis	30 people	49 implants

■**Survival rate**

Single survival rate	1.000-49/1499=1.000-0.033=0.967	Survival rate 96.7 %	
	Case which removed or fell out before the placement of prosthesis	7 people	8 implants
	Case which removed or fell out after the placement of prosthesis	23 people	41implants
Survival rate after installing prosthesis	**1.000-41/1491=1.000-0.027=0.973**	**Survival rate**	**97.3 %**

* Materials are offered by Dr. Kinebuchi

Kunubuchi: The AQB implant cases of approximately 1500 that I conducted from the time at Mitsui Memorial Hospital up to now have been included in this analysis. There have been 49 failure cases that consist of implants that were removed as a result of infection at the initial stages, therefore giving survival rate of 96.7% with a simple calculation. In the 49 cases, there were examples where the bones were thin to the extent that the implanting even with the socket-lift technique were difficult; or where the great degree of indentation on the buccal side of the bone had resulted in bone fissure, and the HA coating layer had become exposed, to which thin bone fragment was used to facilitate the implantation. The majority of the cases were challenging as demonstrated by the following example: a case whereby the looseness of the implant would not disappear even a month after the implantation. This would normally be considered for re-implantation, but the fusion with the bone was achieved with temporary fixture. The survival rate of 97%, considering the most of the failure cases involved complex procedures, is quite a good number. This figure would be even higher in examples with favorable conditions including stable bone structures.

Tsutsumi: Also from my experience, there are several cases starting from the clinical trials that have been observed with favorable outcome, for over 20 years after the operation.

There have been over 500,000 AQB implants installed in Japan, with the application of internationally patented recrystallized HA coating technology. As mentioned in Part 7 - 'Statistical analysis of the clinical implanted state and implant cases with various AQB Implant types and the model', by taking few key points into consideration, satisfactory outcome from the actual surgery should be possible.

For safe and secure operation with AQB

Selecting one-piece, T-type and two-piece types

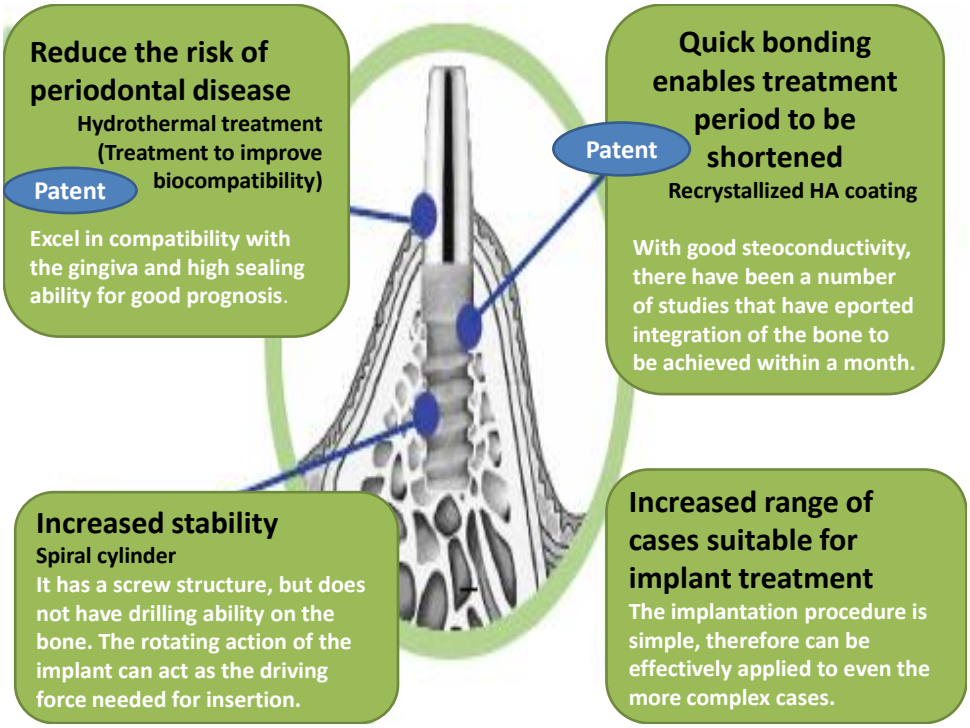

Fig. 5 The main properties of AQB one-piece implant

Tsutsumi: The major characteristic of AQB Implant is the fact that one-piece type is the mainstream product (Fig.5). The statistics show that 85% of the current practices have been using one-piece type. I would like to ask the professors of their views from practices regarding the case suitability of the one-piece type, and its limits of indication; as well as the criteria for choosing T-type and two-piece type.

Kinebuchi: The AQB Implant development has been conducted fundamentally with the one-piece one-stage type, and as I have mentioned in the chapter of 'Treatment plan', I consider that one-piece type can be utilized in most of the cases. The advantages of AQB one-piece implants are that it consists of 6 mm root fixtures with 3 mm diameter, that are not in other implant systems, in its product lineup. With the excellent property of recrystallized HA in quick fusion with the bone, the thickness helps to increase the interacting surface area therefore enabling it to be applied to the cases where the vertical height of the alveolar bone is insufficient. The operation to the alveolar bone with lack of horizontal bone quantity can be performed with the application of 3 mm diameter implant. The major advantage of AQB is the large variety in size, allowing implant body with suitable length and width to be inserted into the bone structure of various dimensions.

Kuroyama: I have personally experienced that the one-piece type can be applied to those cases where two-piece two-stage type have been recommended, such as to the GBR technique or immediate loading. However, in situations where bone augmentation is required and the risk of contracting infection at the initial stages, the application of two-piece two-stage type may be more suitable, and reduce the infection risk. As I touched on the subject in Part 2, Chapter 4 'Treatment plan' of this book, I consider one-piece implant as the first-line choice; the two-piece type where parallel insertion, and angle adjustments are required; and T-type where there is a risk of subsidence into the bone or require strength, in order to achieve good clinical progress.

Miyazawa: I don't agree with the notion that two-piece type to have higher degree of freedom, in terms of prosthetic restoration. The crown arises from the tooth cervix in both one-piece and two-piece types, and there is no distinct difference between these. The issue of hygiene is often brought up as the problem of

the one-piece type, but in my experience of implanting two-piece type to the right and one-piece type to the left of a edentulous maxilla (Fig. 6), the state of oral hygiene has continuously been significantly better with the one-piece type.

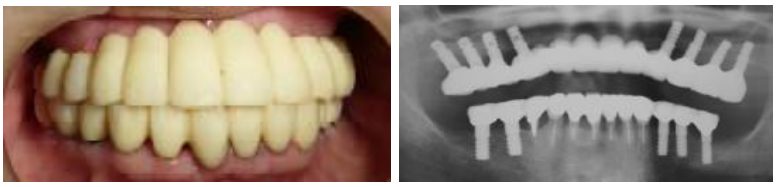

Fig. 6 A case in which two-piece type was installed to the right and one-piece type to the left side of the edentulous maxilla.
Intraoral image (left) and panoramic radiographic appearance (right) taken roughly three years after surgery. Superstructures are all hybrid crowns; gingival inflammation on the left side to which one-piece implant installed was only slight, but shows exposure of HA coating on the cervical region. Exposure of HA coating on the cervical region on right side to which two-piece was installed was not observed, but showed gingival inflammation.

Tsuyama: The current implant treatment expected by both the patients and the practitioners are with the four following points: ① safe and secure operation, ②long-term stability, ③ shortening of the time required for the overall treatment, with immediate loading, ④ reducing the degree of surgical invasion. The shortening of the treatment period has been considered by most of the present implant systems. There is no doubt that the use of one-piece type is advantageous to meet all of these four requirements. I have been investigating the limits of one-piece one-stage type to clarify the potential application of one-piece type in those clinical examples where the one-piece type had not been recommended such as to the bone that has less than 5 mm in vertical bone quantity. With the introduction of T-type, the range that one-piece one-stage type can be applied to have increased even further. Even the implantation to the maxillary molars with less than 3 mm bone width in which primary stability could not be established previously, can now be achieved with the application of T-type.
Tsutsumi: The T-type, from my experience, has shown possibility of its application to the maxillary molars that have particularly soft bone structures. It has been two years since T-type was first introduced, so the long-term observation of the case will need to ve conducted.
There are one-piece, T-type, and two-piece types a wide variety to choose from within AQB (Fig. 7), thus requiring accurate diagnosis and suitable procedures to be conducted accordingly with the findings to maximize the excellent properties of AQB.

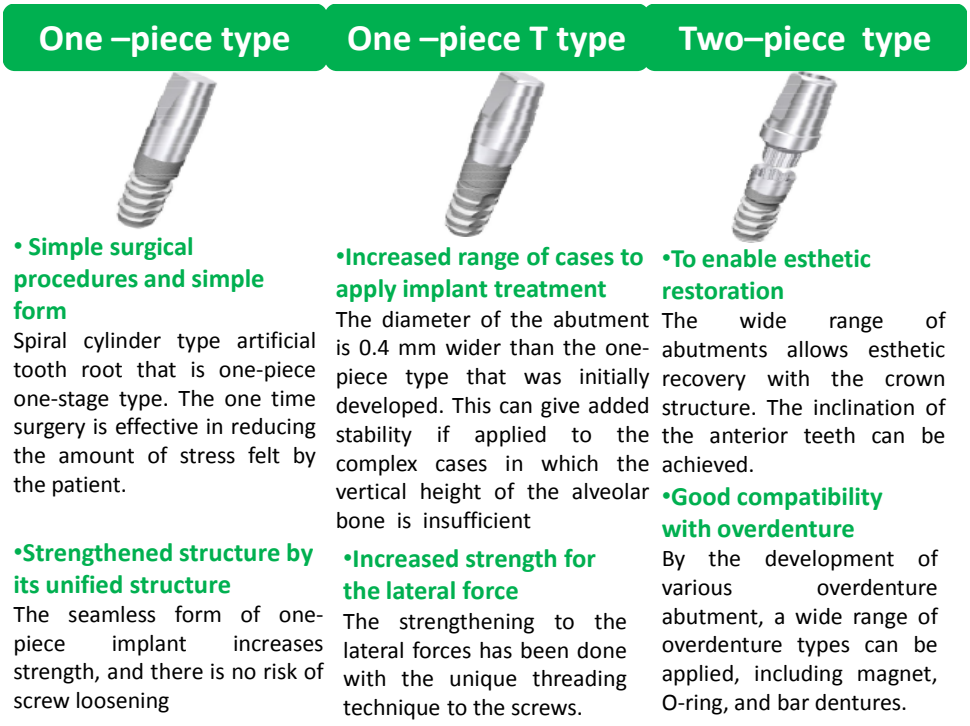

Fig. 7 Lineup of AQB implant products

For safe and secure operation with AQB

What is the safe and secure surgical procedure facilitated by the bone augmentation?

Tsutsumi: Now, I would like to discuss the factors necessary in operation to achieve favorable long-term outcome. In particular, bone augmentation procedure has become one of the most invaluable techniques in current implant treatment. Tell us with how you have applied this technique to the clinical practice and the advice as to how to achieve good outcome.

Kinebuchi: I consider the basic technique is to open the flap, to place a suitable size implant to the area with favorable conditions with one-piece type, a concept which is fundamentally different to the method with which the two-piece type is inserted to a position where there is lack in bone quantity, facilitated by the bone augmentation procedure with top-down treatment. However, to the positions such as the anterior region of the maxilla where esthetics is required, bone extracted from the maxillary tuberosity or the mandibular mental region is used to graft to the deficient part of the bone. In the mandibular region where the vertical bone quantity is lacking, socket-lift technique that uses spiral drill to pierce through the bone is employed (Part 6, Chapter 3- 'Socket-lift method with drilling through the bone'). Sinus-lift procedure is a relatively advanced technique that requires surgical training, therefore should not be considered lightly for its application.

Tsutsumi: Do you use bone filling material with socket-lift procedure?

Kinebuchi: By elevating the schneiderian membrane, the created space becomes filled with platelets so I have not used bone filling agents. The bone is regenerated even with titanium implants, but I have experienced the rapid regeneration of the bone with recrystallized HA coating.

Miyazawa: I also practice with placing the importance of maximizing the use of the residing bone. Implantation is desired to be conducted with full consideration as to the vertical bone resorption that occurs over the years. The importance lies in taking multiple factors into account including specific properties of implants: such that implant is only displaced a distance of 5 μm longitudinally, compared

to 30 μm with natural teeth; or that it is weak in the longitudinal direction; and the strength of alveolar bone in order to derive and achieve suitable occlusal pressure. This is probably the best preventative measure against postoperative infection, overload and bone resorption from arising. To conduct safe and secure bone augmentation procedures I consider socket-lift (Part 6, Chapter 3 'A case where a trephine bur was used for maxillary sinus elevation') to be clinically effective with the use of trephine bur to lift the bone to the maxillary sinus.

Kuroyama: Indeed, the bones augmented with techniques such as GBR are required to be conducted with having considered the probability of bone resorption with time. I also feel that technology to synthesize artificial bone that is highly effective needs to be developed that can replace the autogenous bone graft, particularly to ease the damages caused to the region of in which large amounts of bone has been extracted. β-TCP has shown high clinical efficacy as a bone filling agent, but I am contemplating the application of α-TCP that have been found to enable large regeneration of bone, in the clinical practice in the future. As a reference, I have included the experimental data of the application of samples of titanium plasma coated with α-TCP to the femur of dog, during my time at graduate school (Fig. 8). The soft X-ray radiograph of the bone filled with α-TCP, at 12 and 48 weeks, shows significant bone generation compared to that of the control in which HA was inserted.

There has been recent rise in immediate loading technique, as mentioned by Dr **Tsuyama**: The pros of this technique are: 1. Shorten the treatment period, 2. Effective to be applied to the area where bone on the buccal side has been resorbed, and may be subjected to further resorption with the extraction. Compared to implanting after the healing of the extraction cavity, there is added concern of the bone and gingivae in the neck region of the implant to thin down with time. It might be an idea to secure the thickness by placing fixed gingivae to the implant surroundings.

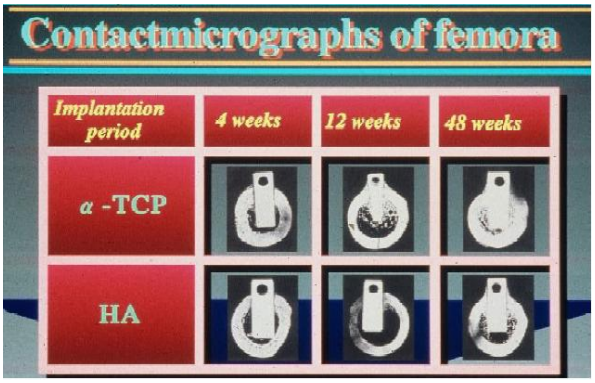

Fig. 8 Soft X-ray appearance of α- TCP and HA coating sample

(Source: Yushiro Kuroyama, Characterization and bone tissue rejection of α- TCP plasma coated titanium material, J. J. Dent. Mater., Vol. 12, No. 6, 773-789, 1993)

Tsuyama: Horizontal bone width of more than 1 mm surrounding the implant is desired. Therefore for an implant of 4 mm diameter, a horizontal bone width of over 6 mm becomes an essential requirement. With regards to the vertical bone quantity, to enable full insertion of the HA coating layer, a length of plus 2 mm vertical bone quantity is required. For a single insertion, implants of over 8 mm length are recommended therefore a vertical height of 10 mm is the minimum requirement. Therefore a condition that qualifies these criteria becomes the initial check point, and the bone augmentation procedures have been employed in situations where these were not met. The best method in which to conduct bone

augmentation procedure, in terms of reducing the risk of infection and shortening of the treatment period, would be to implant with autogenous bone that have adopted the property of osteoindiction from AQB recrystallized HA. There have been cases where sinus-lift techniques done, with only using autogenous bone, have resulted in favorable outcome. I will present the efficacy of this technique with the results from the long-term clinical examples in the future.

Tsutsumi: Lastly, I would like each of you to give us one last advice.

Tsuyama: To conduct safe and secure procedure, the complete insertion of the implant to cover the HA coating with the bone, and complying to this basic rule is fundamental to the success of implant treatment

Kinebuchi: I agree. Also, implant treatment is one that combines all the procedures of oral and maxillofacial surgery. The techniques of incision, detachment, milling, suture, postoperative care and observation is cultivated by the everyday practice of horizontal wisdom tooth extraction and gingival flap operation, therefore it is important not to neglect the general oral surgical practice.

Kuroyama: The success rate of implant treatment has not yet reached 100%, and unfortunately there are examples in which they have to be extracted. Investigating the reasons and the underlined mechanisms scientifically, I believe, is the task that has to be conducted for the future development of implant.

Miyazawa: The determining factors for the prognosis of the implant treatment with regartds to the AQB, I think, is beyond the innate properties of AQB, it all comes down to the mechanical force, occlusal force that is exerted on the implant body via the superstructure, and the extent that the surrounding alveolar bone can withstand this. The superstructures of implants with that of the natural teeth are essentially distinct therefore implementation of 3D stress analysis to derive at an unique occlusal theory may be required in the future.

Tsutsumi: There is no doubt that the practice of implanting technique conducted true to the basics; gradually expanding the scope of its application; and the development of prosthesis that has implemented occlusion unique to the implant will contribute greatly to the improvement in the prognosis of implant treatment.

I hope safe and secure surgery will be conducted in a way to maximize the properties of AQB will be continued.