

Part 7 - Clinical data of AQB Implants

1. Statistical analysis conducted on clinical cases of AQB one-stage type implant since the opening of the clinic

Oral Surgery, Tokyo West Tokushukai Hospital ¹⁾

Oral and Maxillofacial Surgery, Shonan Atsugi Hospital ²⁾

Implant Clinical Society in West Tokyo District ³⁾

Dr. Atsushi Kawai ¹⁾³⁾

Dr. Tsuguo Sano ¹⁾³⁾

Dr. Ario Hashimoto ¹⁾³⁾

Dr. Takeshi Odani ¹⁾³⁾

Dr. Hisatoshi Matsumoto ¹⁾³⁾

Dr. Atsushi Kishima ²⁾³⁾

Dr. Hiroshi Shimizu ³⁾

Dr. Yoshinori Ogawa ³⁾

Dr. Takaaki Watabe ³⁾

Dr. Yohei Kashida ³⁾

Introduction

There has been a recent increase in the demand for implants that have the ability to endure early loading of the superstructures to shorten the treatment times. AQB one-stage implant (ADVANCE Co., Ltd.) that meets this demand has become a popular tool. An implant center was opened with the dental surgery clinic in West Tokyo Tokushukai Hospital in September 2005. The AQB one-stage type implant was adopted as the mainstream treatment. A period of two and a half years has passed since the start.

We conducted clinical analysis of the cases using AQB one-stage implants for 2¹/₂ years during the period of September 2005 to March 2008. The case examples are presented in the following sections with added commentary.

The test targets

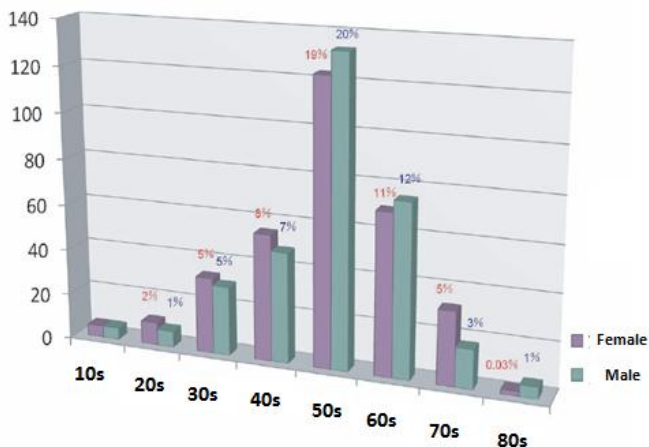
The case examples of 650 individuals treated in West Tokyo Tokushukai Hospital, excluding those referred to from other clinics, during the 2¹/₂ years period between September 2005 and March 2008, were subjected to analysis.

The analysis criteria were: 1. Sex; 2. Average age; 3. Age group; 4. No. of implants installed; 5. Area of implantation and 6. Period till superstructure placement.

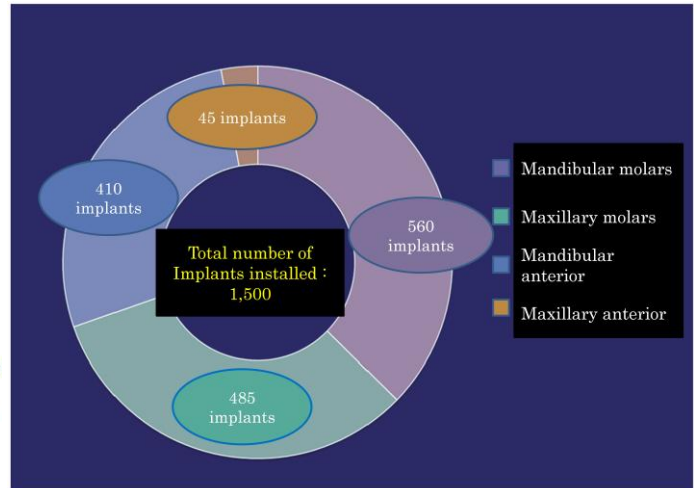
1., 2. Sex, male to female ratio, and average ages

Male: 320 individuals, female: 330 individuals	Average age of male; 54.4 years old
Sex ratio - 1 :1.03	(16 yrs old – 84 yrs old)
	Average age of female; 53.8 years old
	(17 yrs old – 8- yrs old)

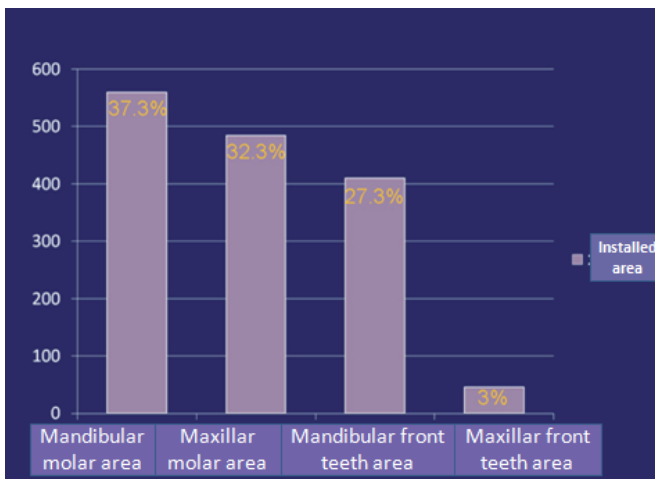
3. Age group



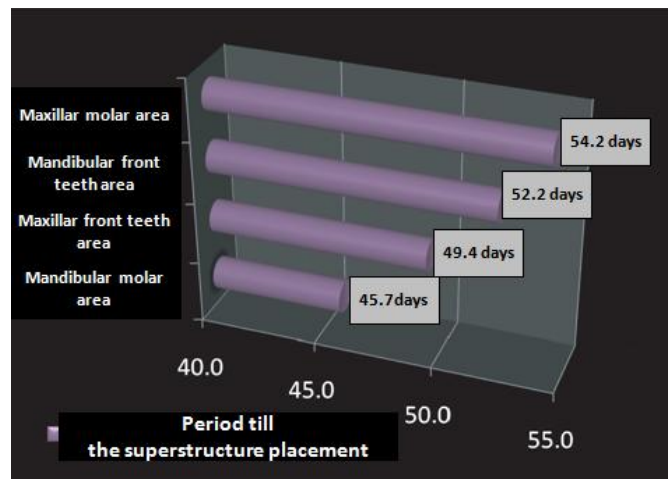
4. No. of implants installed



5. Area of implantation



6. Period till superstructure placement



Discussion

The results showed that a third of the total number of cases was found to be implanted to the maxillary, and another third to the mandibular molars. This finding suggested that there were a significant number of cases that needed the treatment close to the sinus floor that could not be treated in other dental clinics. The average age of both males and females were mid-50s, and the number of cases conducted on individuals in their 50s was significantly higher than in any other age group. This period overlaps with the period in which the tooth loss induced by periodontal disease is particularly prevalent, and thus indicated the implant treatment to be in high demand by this age group as an alternative to bridge prosthesis or artificial dentures.

The period till the superstructure placement was the shortest in the mandibular molars and the longest in the maxillary molars such that the consolidation period of 2 to 2½ months was required for the latter cases. This can be said to be due to the differences in the composition of the bone, since the mandibles have more compacted structure than the maxilla, therefore giving rise to the differences in the treatment time indicating the difficulty in the implant treatment to the maxillary molars.

There have been a recent increase in the number of referrals, for cases of complicated maxillary molars,

made from other clinics to the Tokyo West Tokushuku Hospital, or more specifically, to the implant clinic from other facilities. We consider this to be due to the high success rate with the uses of low invasion, socket-lift technique, which have been given great approval by the sources of referral. This is the result of the high expectation of the method which was established to overcome the weaknesses of the one-stage type implant; and to our responsibility to treat the high risk scenarios (August 24th 2008).

2. Statistical analysis conducted on the clinical cases of AQB Implants performed in the last five years in the clinic.

Omori dental clinic ¹⁾

Section of Oral Implantology, Department of Oral Rehabilitation, Fukuoka Dental College ²⁾

Dr. Keiji Omori ¹⁾²⁾

Dr. Hiroshi Kido ²⁾

Dr. Masaro Matsuura ²⁾

Objective

AQB Implants with a recrystallized HA coating layer of 35 μ m have been shown to rapidly bond with the bone with significant strength, rarely giving rise to loss of implant. AQB Implant system was first developed in 1990 and its clinical trials were initiated in 1992. The cases in which a period of over 1¹/₂ after the placement of the superstructures to AQB implants bodies have been included in the analysis.

Method

A total of 577 implants in 305 areas of 196 patients, placed with superstructures from February 1998 to January 2003 were subjected to analysis. The cases were categorized according to: 1. Age; 2. Sex; 3. Implanted area; 4. Period till superstructure placement; 5. Implant size; 6. If bone augmentation technique was applied; 7. Survival rate.

Results

Out of the total of 196 patients enrolled onto the clinical trials, 135 (68.9%) were female and the remaining 61 were male, ranging from 21 to 87 years with the average age of 51.2. Over half (55.6%), 321, implants were installed to the mandibular molars; 175 (30%), to the maxillary molars; 51 (8.8%) to the maxillary anterior; 27 (4.7%) to the mandibular anterior. The sizes of the fixture used were with 4 mm diameter with 10 mm length in 280 implants (48.5%); and 4 mm diameter with 8 mm length in 173 implants (30.0%).

There were 66 cases (21.6%) in which the bone augmentation procedures were performed. There were ten implant prosthesis (1.7%) that came out in which two of these were before the superstructure placement, and the remaining eight occurred after superstructure placement.

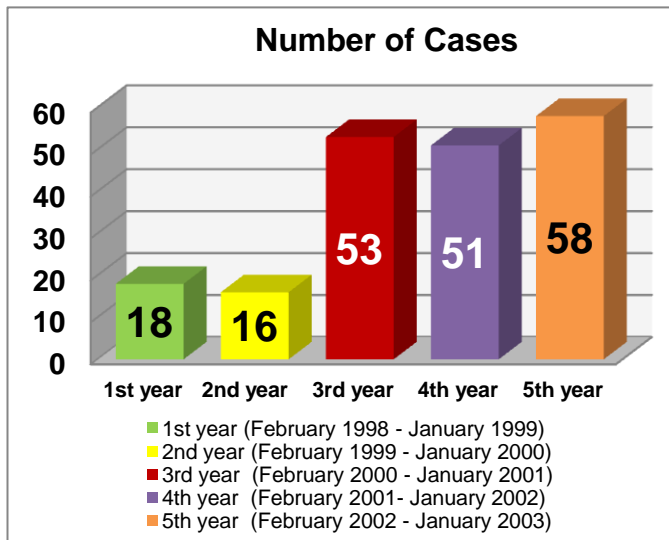
Discussion and conclusion

The survival rate of the implants from 1¹/₂ to 6 years was 98.3%, and the implants lost accounted for 10 of the cases. The average number of days from the implantation to loading was 54 days for the mandibles, and 70 days for the maxilla. Even though these were significantly shorter than the implant treatment protocols of the past, the progress made was favorable, indicating the clinical efficacy of AQB Implant system as a highly effective implant treatment. In particular, the one-piece type implant that requires no rotational forces at the time of abutment placement was thought to be suitable for immediate implantation after extraction and immediate loading techniques.

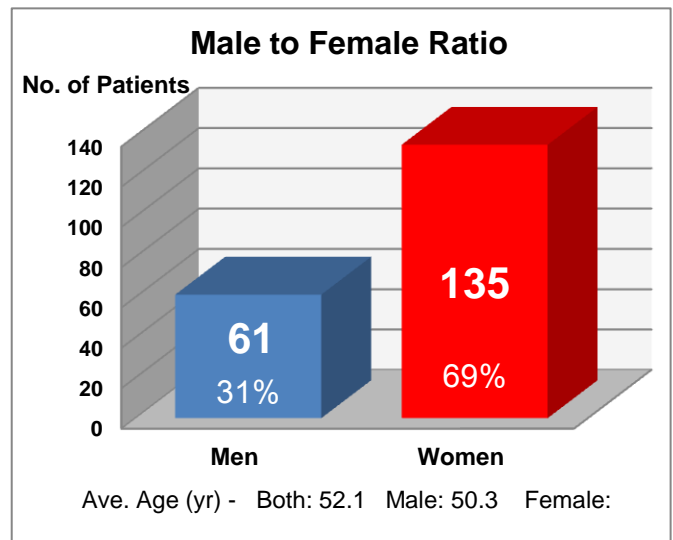
Summary of survey

Investigation period	From February 1998 to January 2003
No. of cases	305 cases
No. of patients	196 people
Total number of implant installed	577
Average number of implant per patient	2.9
The maximum number of implants implanted in a patient	21 implants
Product used	AQB implant of ADVANCE CO., LTD

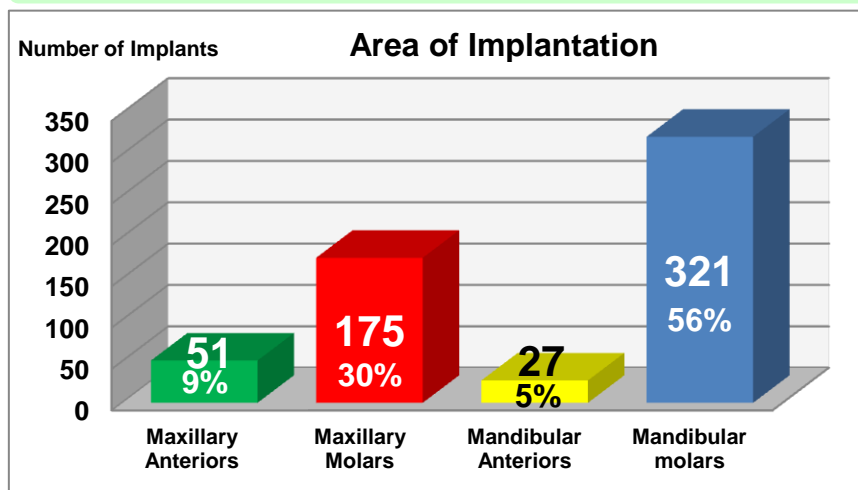
The number of cases per year



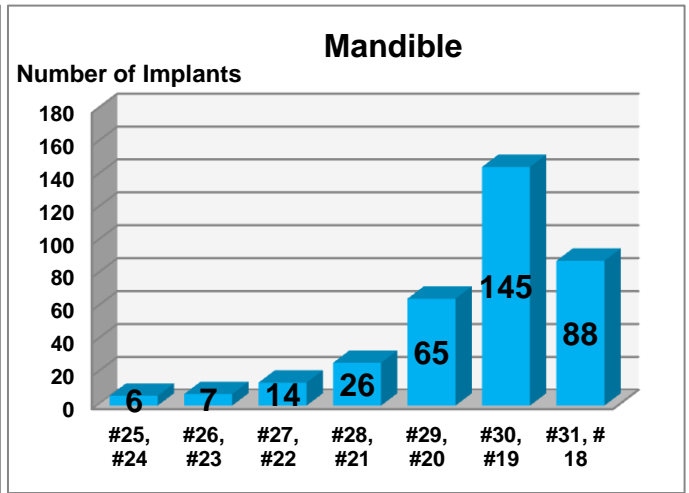
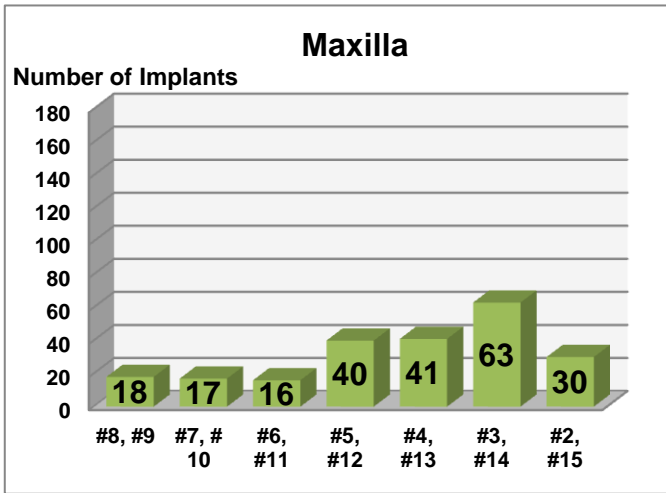
Age and sex of patients



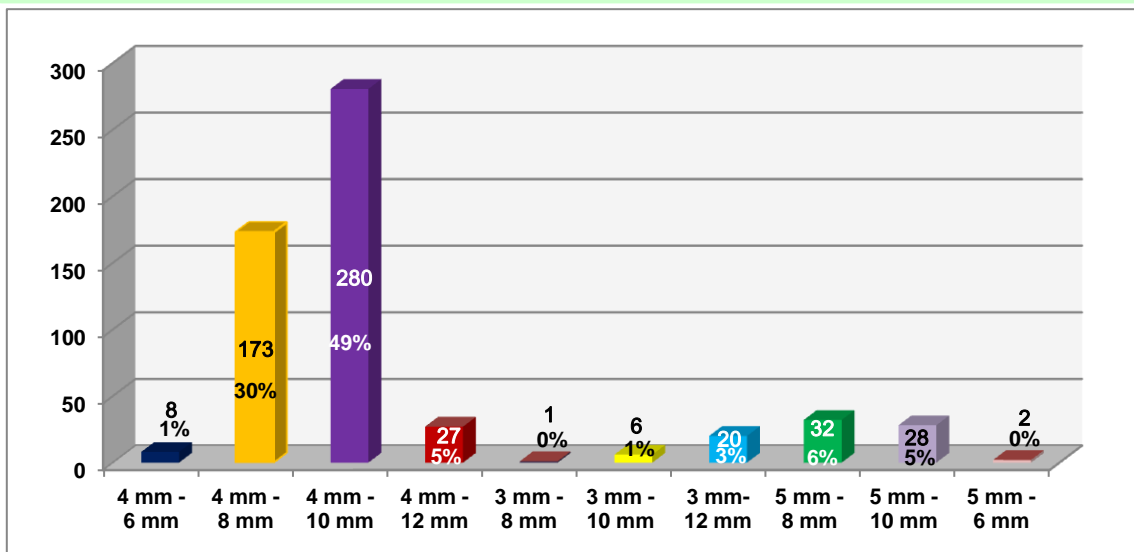
Area of Implantation 1



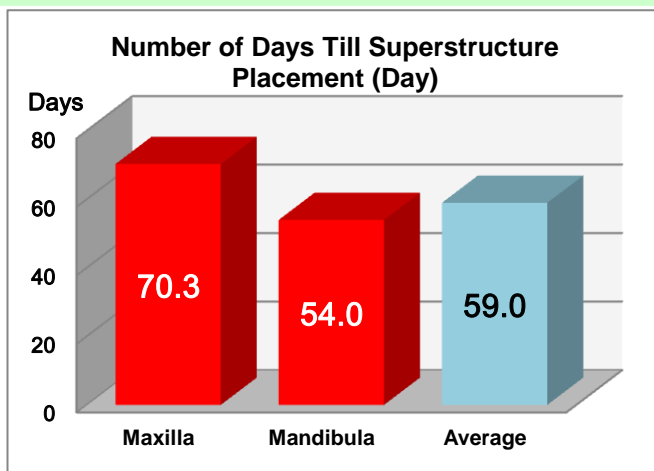
Area of Implantation 2



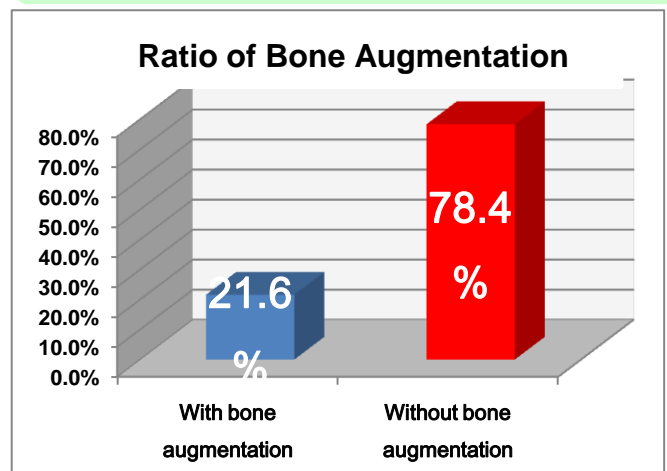
Sizes of Fixtures



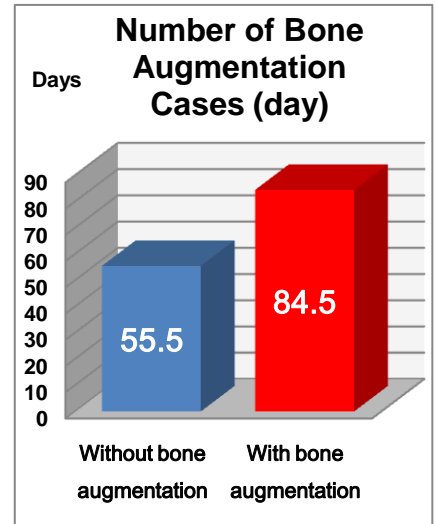
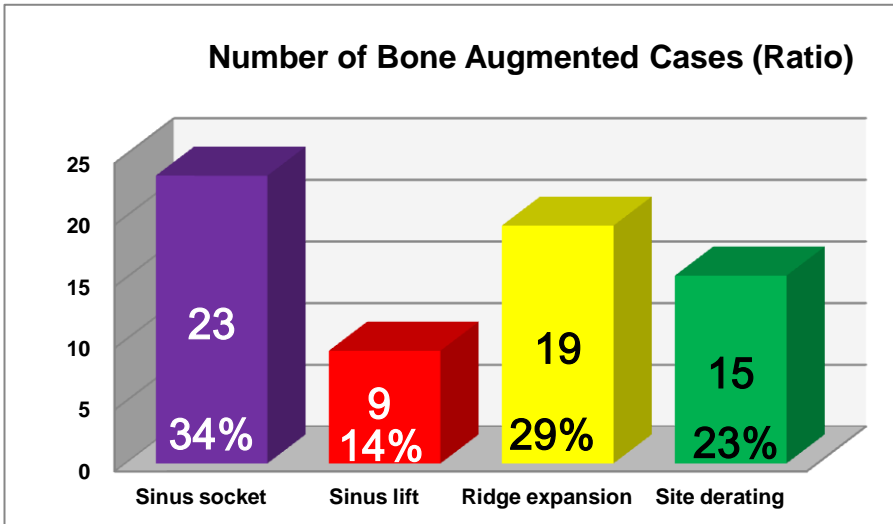
Average No. of days till Superstructure Placement



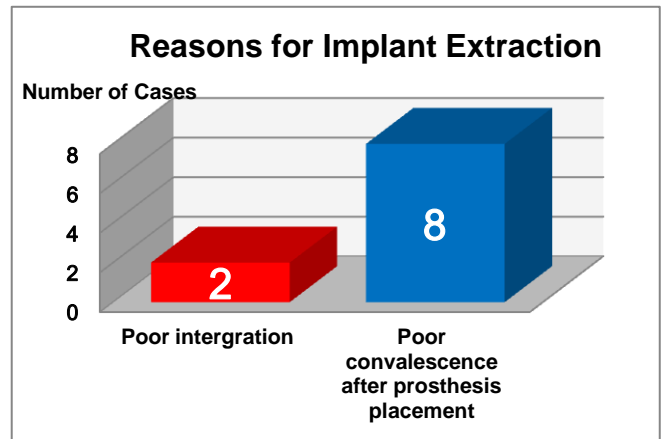
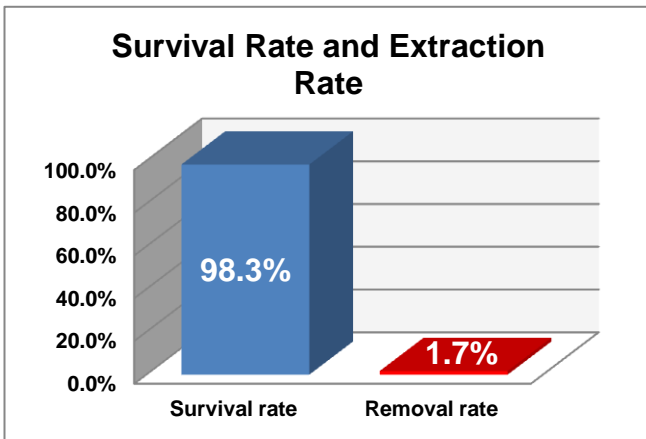
Ratio of Bone Augmentation in All of the Cases



Period till the Superstructure Placement of Bone Augmentation Cases



Survival Rates and Removal Rate of Implant and Reasons for Extraction



3. Statistical analysis of the clinical implanted state and implant cases with various AQB Implant types and the model

Vice Director of Medical Clinic, Ministry of Foreign Affairs Division of Health and Welfare

Dr. Yoshichika Tsutsumi

Introduction

AQB implants treated with recrystallized HA are known to integrate rapidly with jaw bone, and have high biocompatibility with the gingivae. In order to re-assess its properties and clinical efficacy, the clinical evaluation of the AQB implants were conducted with regards to the implanted state, clinical progress, and survival rate with the various types and forms of the AQB implant installed to the upper and lower mandibles.

Test subjects

The implanted states of 139 cases, with a total of 329 implants (on average 2.37 implants/case), installed within a period of two years and two months, between October 2006 to December 2008, were evaluated with respect to the type and the model of AQB implants. These were divided into the anterior, right and left molars for the upper and lower mandibles to investigate and analyze each implant types with their clinical progress and the survival rates.

The sexes, male to female ratio, as well as the average age of test subjects are as shown in Table 1.

	Male	Female
No. of patients	49	90
No. of patients (Total)	139	
No. of patients (Comparison)	01:01.8	
Average age	62	61.4
Age range	37-82	33-83

Table 1 Sex, male to female ratio, and average age

The type, form and the number of implants in each region

The type and the number of AQB implants installed into the upper and lower mandibles; and left and right molars are summarized in Fig. 1, and the number of each implant types, given in Table 2. The implant type and the model have been chosen on the grounds of the area of implantation and the jaw bone/gingivae, the adjacent and opposing teeth. With regards to the one-piece type, T-type has been selected over the straight type since it was placed on the market.

The figures show that the number of implants installed into the anterior teeth is significantly less than those to the molar regions, with 28 implants (8.5%) within which only four (12%) to the lower mandible, compared to 136 to the upper, and 165 to the lower mandibular molars resulting in 1:121 ratio. The numbers of implantations to the left and right molars were relatively equal on both sides with 149 to the left, and 152 to the right.

In comparing the types of implants used to the upper and lower mandibles: 76 one-piece type and T-types; and 84 two-piece types were implanted into the maxilla; 149 one-piece type and T-types; and 20 two-piece

types to the mandibles. This resulted in 1:1.11 ratio for the maxilla and 1:0.13 ratio for the mandible, showing that the significantly higher usage of two-piece type in the maxilla, and the one-piece and T-types in the mandible. These results largely reflect the presence of the maxillary sinus.

		Maxilla				
Right	One piece: 17	One piece: 1	One piece: 15	Left	One piece: 15	
	T type: 21	T type: 1	T type: 21		T type: 21	
	Two piece: 36	Two piece: 22	Two piece: 26		Two piece: 26	
	Total: 74 implants	Total: 24 implants	Total: 62 implants			
<hr/>						
Right	One piece: 45	One piece: 0	One piece: 49	Left	One piece: 49	
	T type: 26	T type: 1	T type: 28		T type: 28	
	Two piece: 7	Two piece: 3	Two piece: 10		Two piece: 10	
	Total: 78 implants	Total: 4 implants	Total: 87 implants			
<hr/>						
		Mandible				

Fig. 1 – The type and the number of implants in each region of the oral cavity

Type	Number
One-piece	127
T-type	98
Two-piece	104
Total Number	329

Table 2 - The number of each implant

The number of one-piece type and its models categorized with respect to the area installed

The number of one-piece type installed to each region in the upper and lower mandibles and its model type were summarized in Fig 2.

The implantation of on-piece type to the anterior maxilla was found to be 1/ 127 (0.79%), a significantly small number. The total number of one piece type was 33 to the upper mandible, and 94 to the lower mandibles, resulting in 1:2.85, indicating its higher usage rate to the lower mandibles.

In comparing the model types used, 4SS were employed in 20/33 cases (60.6%) to the maxilla showing a high selection rate. Meanwhile, to the lower mandibles, 29, 4MS (30.9%); 20, 5SS (21.3%); and 15, 5MS (16.0%) were chosen.

The diameters of the implants used in the maxilla were: 28 for 3 and 4 mm; and 5 for 5 mm, and in the mandible: 52 for 3 and 4 mm; and 42 for 5 mm. These resulted in 1: 0.18 for maxilla and 1:0.81, for the use of 3 & 4 mm against 5 mm diameter implants to the upper and lower mandibles, respectively, indicating that implants of thicker diameter to be used to the lower mandible.

Maxilla		
468: 1		4SS: 11
4SS: 9		4SM: 1
4SM: 3	3MS: 1	4MS: 1
4MS: 1		5SS: 1
566: 1		5SM: 1
5SS: 1		
5SM: 1		
Total: 17 implants	Total: 1 implant	Total: 15 implants
Right		Left
3MS: 2		3MS: 1
4SS: 4		4SS: 8
4SM: 3		4SM: 3
4MS: 14		4MS: 15
566: 1		566: 2
5SS: 7		5SS: 13
5SM: 4		5SM: 2
5MS: 10		5MS: 5
Total: 45 implants	Total: 0 implant	Total: 47 implants

Mandible

Fig. 2 –: The number of one-piece type installed to each region

The number of T-type and its models categorized with respect to the area installed

The number of T-type installed to each region in the upper and lower mandibles and its model type were summarized in Fig 3.

In comparing the implantation of T-type with respect to the area, the implant to the anterior region in both upper and lower mandibles were found to be significantly low with installation of one each, thus resulting in 2/98 (2.04%). The ratio of the upper to lower mandible with 43 and 55 resulted in 1:1.28, relatively higher to the mandible. This indicated that the application of T-type to the maxilla has increased in comparison to the one-piece type, reflecting its improved ability to achieve primary stability. The number of T4SS model applied was the highest with 20/43 (46.5%) to the maxilla; T4MS with 26/55 (47%) was the highest for mandible followed by T4SS with 15/55 (27.3%).

The number of various diameters of the implants used were 31 for 3 and 4 mm; 12 for 5 mm in the maxilla; and 49 for 3 and 4 mm; and 6 for 5 mm in the mandible, thus resulting in the ratios of 1:0.39 and 1:0.12 for maxilla and mandible, respectively. The ratios indicated that the implants with thicker diameter were used in the maxilla, which was opposite to the one-piece type. This can be owing to the fact that the number of socket-lift techniques performed on the maxilla, where tapered region of T-type with thicker diameter has been chosen to aid the primary stability.

Maxilla		
T46S: 1	T3 mm : 1	T4SS: 8
T4SS: 12		T4SM: 4
T4SM: 2		T4MS: 2
T4MS: 1		T5SS: 6
T5SS: 5		T5SM: 1
Total: 21 implants	Total: 1implant	Total: 21implants
Right		Left
T3MS: 2	T3MS: 1	T4SS: 7
T 3 mm: 1		T4SM: 1
T4SS: 8		T4MS: 14
T4SM: 2		T4MM: 1
T4MS: 12		T5SS: 3
T5SM: 1		T5SM:2
Total: 26 implants	Total: 1 implant	Total: 28 implants

Mandible

Fig. 3 –The number of the T-type installed to each region

The number of two-piece type and its models categorized with respect to the area installed.

The number of two-piece type installed to each region in the upper and lower mandibles and its model type were summarized in Fig 4.

In comparing the implantation of two-piece type with respect to the area, the implant to the anterior region to the maxilla was 22 and 3 to the mandibles, thus resulting in the total of 25/104 (24.0%), which showed the highest selection rate than other implant types. This frequent use in the anterior region is to gain esthetics by angled features.

The number of implants to the maxilla was 84, and whereas to the mandibles was 20 giving the ratio of 1:0.24, the significantly higher use to the maxilla to reflect its application with consideration to the maxillary sinus in socket-lift technique.

Maxilla		
4082: 16	4082: 9	4082: 21
4102: 15	4102: 12	4102: 5
5082: 5	5102: 1	
Total: 36 implants	Total: 22 implants	Total: 26 implants
Right		Left
4082: 2	4082: 1	4082: 3
4102: 5	4102: 2	4102: 7
Total: 7 implants	Total: 3 implants	Total: 10 implants

Mandible

Fig. 4 – The number of two-piece types installed to each region

As to the model types used, out of the 104 two-piece types implanted into the upper and lower mandibles: 52 (50.0%) for 4082; 46 (44.2%) for 4102; 5 (4.8%) for 5082; and 1 (1.0%) for 5102.

The number of 4 mm diameters applied were 98; and 6 for 5 mm diameters in total to both upper and lower mandibles, giving 1:0.06 ratio, indicating a significantly higher selection for the 4 mm diameter type.

The number of model type used in conjunction with the socket-lift procedure

The AQB Implant that has improved osteoinduction and bone integration have also shown high clinical efficacy in conjunction with the socket-lift procedure.

The number of the model types used in various region of the maxilla is summarized in Fig. 5.

The socket-lift procedure had been conducted in 34 of the 329 cases in total thus in 10.3% of the cases in 1:0.62 (right maxilla: left maxilla) ratio, with higher incidence on the right.

The types of implants used were in the order of T-type, two-piece and one-piece types, with 18, 9 and 7 implants, respectively, giving rise to the ratio, 3.9:1.3:1. There was no significant difference in clinical progress with the different types, and all have shown satisfactory outcome.

Maxilla	
Socket lift: 21implants	Socket lift: 13 implants
4SS: 3	4SS: 1
T4SS: 5	T4SS: 3
4082: 4	4082: 3
468: 1	4MS: 1
T4SM: 2	T4MS: 1
4102: 1	T5SS: 4
5SM: 1	
T5SS: 3	
5082: 1	
Right	Left

Fig. 5 The number of the types installed to each region in cases with socket lift:

Other factors affecting the selection of the model type from other clinical cases

The cases that were deemed worth mentioning in these statistical analyses have been summarized in Fig. 6. In these particular cases, there were 10 cases (10 implants) in which the selected model type of the implants were different from what was initially planned. Over half, 6 cases, were presented with insufficient bone quantity; 2 of the cases for issues with clearance; 1 for the insufficient depth due to difficulties in the bone milling; and one where the implant was changed to two-piece type due to perforation of the maxillary sinus floor, were given as the reasons. There was another example in which due to the exposure of HA coating after its insertion, the HA was removed, but all of these examples have shown satisfactory progress and no issues have been detected.

There were seven implants (2.1%) in five cases in which recovery procedure was conducted. These were all done to the right maxilla and the details of which have been summarized in Table 3. Two out of the five cases have undergone the procedure twice. The reason for these failures were due to overload, but in an

attempt to clarify the conditions in which the implant fell out, parameters such as the time till the fall out; state of the bone; and the surgical conditions were summarized (Table 4).

In analyzing the failed examples, the main reason was discovered to be the loss of integration with the bone from the overload, and three of these cases presented with the thinness of the bone, between 1 mm to 3 mm, resulting from socket-lift technique, and the remaining two cases were those, where the loading from the prosthesis could not be prevented following the operative procedure.

The recovery methods are to be conducted having confirmed that there are no load exerted from the dental prosthesis, and reduce the amount applied as much as possible. Next, the place the implant to the area with sufficient bone quantity, and either select two-piece type that is less affected by the loads till establishing firm connection with the bone, or T-type that has good primary stability.

During the period of 2007 to 2008, there has not been any case in which re-implantation was conducted, when taking the past practices with regards to the selection of the type and model; the area of implantation; limit the amount of weight exerted onto the installed implant, as well as the increased number of applications of T-type implants into consideration.

Maxilla		
Recovery: 5 cases (7 implants) * Details described in Table 3		Changed model: 2 • One-piece → 4082: 1 Maxillary sinus perforation • φ 5 → T4SS: 1 Lack of bone quantity
Total: 7 implants	Total: 0 implant	Total: 2 implants
Right		Left
Changed the model: 4 • φ 4 → 3MS: 2 Lack of bone shortage • 4MS → 4SS: 1 Unable to dig • T4MS → T4SS: 1 Clearance		Coating layer exposed: 1 (One-piece) Model change: 4 • φ 4 → 3MS: 1 Lack of bone shortage • 4MS → 4SS: 2 Lack of bone shortage • 5MS → 5SS: 1 Clearance
Total: 4 implants	Total: 0 implant	Total: 5 implants

Mandible

Fig. 6 Special cases: The number of the types installed to each region

1 st Time	2 nd Time	3 rd Time	The reasons for the fall out
5082	T5SS	4082	Bruxism and exert load before osseointegration
4082	4102		Traumatic occlusion (Crossbite)
4SS	T5SS		Lateral excessive load from buccal
468	566	T4ss	Overload by final prosthesis
4082	4082		No bone adhesion due to the overweight from the denture base

Table 3 – The number of recovery cases and the types and the model of the implants

Number	Dates of surgery (column below: days)			Details (e.g. State of the bone, surgical procedures)
	1 st Time	2 nd Time	3 rd Time	
1	2007/2/24	2007/6/23	2007/12/22	Since the bone width was merely 2 mm in thickness, out of the two, two-piece types, 4082 and 5082, installed, 5082 fell out. T5SS was re-implanted but fell out for a second time, therefore 4082 was implanted to the position No. 15 shifting from No.14. # 3and installed 4082. Convalescence has been well.
		199 days	182 days	
2	2007/3/7	2007/7/11		Type 4082 that was implanted, fell out, so 4102 type was re-implanted at a slightly different location. Satisfactory progress has been made.
		126 days		
3	2007/3/24	2007/6/2		4SS implant installed with socket-lift to a narrow piece of bone that was 1 to 2 mm, fell out. T-type T5SS was installed to the same position, and satisfactory outcome has been achieved thus far.
		70 days		
4	2007/4/14	2007/7/4	2008/4/7	468 model of one-piece type implant was placed with socket-lift technique to a narrow piece of bone with 2 to 3 mm, but fell out. therefore second attempt was done with 566 type. This fell out again after 9 months therefore the type was changed to T4SS to insert to a shifted position, and a satisfactory progress has been made so far.
		81 days	278 days	
5	2007/6/27	2007/9/3		Three two-piece 4082 models were implanted to a position where the gingivae were found to be thick, and a significant amount of bleeding resulted during the operation. One of the implants fell out from the weight exerted from the floor denture therefore 4082 model was re-implanted, having removed the weight. The progress has been satisfactory thus far.
		68 days		
Ave. number of days		92.8 days	230 days	Survival rate of AQB implant: 97.87%

Table 4 – Treatment details of the fall out cases (the number of cases are the same as those in Table 3)

Observation

It has been 25 years since the clinical studies were initiated in the oral cavities of humans with AQB implants that were developed with novel recrystallized HA coating employing international patented technology. The number of AQB implants installed has surpassed 500,000 and have shown clinical efficacy without encountering any significant problems.

The factor supporting this clinical success is the recrystallized hydroxyapatite coating technology. This enables the rapid and sufficient bonding with the bone, and the high biocompatibility with the gingivae acts as an effective barrier for the invasion of pathogens.

In the present statistical analysis, a total of 139 cases with 329 implants (av. 2.37/case) during the two years and two months, during the period of October 2006 to December 2008 were subjected to analysis. The survival rates from these cases were shown to be 97.87%. It was also shown from inspection and analysis of the details of the cases where recovery intervention was required; by considering the key points, it was possible to conduct the treatment procedures without any mistakes. The key points are as shown below:

- ① By preventing the exertion of weight and movement onto the implant with occlusion, prevent the initial bonding with the bone to be disrupted.
- ② Inspect the conditions of the bone, and ensure that the implant is placed into a position in which sufficient bone quantity is present, and in the direction that is less likely to be subjected to lateral movements.
- ③ Select a type and model of the implant that is suitable for the observed state of the bone, and construct a hole with a depth that is adequate to fully insert the implant body without exposing the HA coating.
- ④ The superstructure design should be one that prevents excessive amounts of weight loaded onto the implant, with a parameter such as the occlusal area and dispersion of stress.

When the restoration procedure was conducted on 5 cases with 7 implants, while bearing the above points in mind, a satisfactory progress was seen and outcome alongside all of the other cases. The AQB implants with its high biocompatibility, has no need for special procedures to be conducted, and a good clinical results can be achieved simply by following the general procedures with utmost care.

I have not yet encountered any cases in need of recovery interventions having implemented the past experiences, and currently experiencing the excellent properties of AQB implants.