Bone Added Osteotome Sinus Floor Elevation with Simultaneous Placement of Branemark Ti-Unite and ITI SLA implants

Nam-Won Kang[1] · Ui-Won Jung[1,2] · Seong-Ho Choi[1,2,3] · Kyoo-Sung Cho[1,2,3] · Jung-Kiu Chai[1,2] · Chong-Kwan Kim[1,2,3] · Chang-Sung Kim[1,2,3]

[1]Department of Periodontology
[2]Oral Science Research Center, College of Dentistry
[3]Brain Korea 21 Project for Medical Science, Yonsei University

Ⅰ. Introduction

The placement of implants in the posterior maxilla is occasionally limited by insufficient bone volume as a result of alveolar atrophy or pneumatization of the maxillary sinus. This clinical problem can be resolved by sinus augmentation using various surgical procedures, including an onlay augmentation of the alveolar crest[1,2], Le Fort I osteotomies with an interpositional bone graft[3,4], lateral approach sinus augmentation [5-7] and osteotome sinus augmentation[8-11]. The placement of the implants in a bone- grafted maxilla has been reported to be successful as a 1-step approach with sinus augmentation or in a 2-step approach after sinus augmentation. However, when placed in the bone-grafted maxilla, a lower survival rate of machined surface implants compared with rough surface implants has been reported.

In 1994, a less invasive sinus floor elevation procedure with simultaneous grafting and the immediate placement of implants was introduced by Summers[8]. Using the Summers osteotome kit[8,9], which was specifically designed for this procedure, the pre-existing crestal bone is displaced toward the sinus floor as the osteotomes are inserted. Various types of graft materials and implants can be used in this surgical procedure. Clinical case reports and studies on the BAOSFE proce-

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Correspondence author : Chang-Sung Kim, Department of Periodontology, Oral Science Research Center, College of Dentistry, Brain Korea 21 Project for Medical Science, Yonsei University. 134 Shinchon-Dong, Seodaemun-gu, Seoul, Korea.
Phone: +82-2-2228-3186 Telefax: +82-2-392-0398 E-mail: dentall@yumc.yonsei.ac.kr

dure with the simultaneous placement of implants showing a relatively high survival rate in both the Brånemark(91.4 to 100%) and ITI SLA implants (94 to 98 %) have been published[10-15]. However, no comparative clinical study was available on the Brånemark Ti-Unite and ITI SLA implant.

Clinical and radiographic studies on the dimensional change in the grafted bone have also been reported[16,17]. It was reported that all the graft materials resulted in a radiographic reduction ranging from 0.79 to 2.09 mm over a 3-year follow-up. However, it was not determined whether this reduction in graft height occurred during the initial healing period or was an ongoing process. Recently, Hatano et al. assessed the long-term changes in the sinus-graft height after a maxillary sinus floor augmentation with simultaneous placement of 18 implants. The results showed that the graft height decreased during the first 2~3 years after augmentation, but all subsequent changes were minimal.

The aim of this study was to evaluate and compare the clinical results of the Brånemark Ti-Unite and ITI SLA implants placed simultaneously using BAOSFE procedure and to assess the change in the graft height radiographically in these two different implant systems after the BAOSFE procedure during the initial healing period.

Ⅱ. Materials and Methods

1. Patients

Twenty two patients(10 women and 12 men, mean age of 50 years, age range of 20 to 65 years) with severe atrophy of the alveolar process in the posterior maxilla were treated at the Department of Periodontology, College of Dentistry, Yonsei University. None of the patients showed signs and symptoms of sinus and intraoral disease. The patients were provided informed consent to participate in this clinical study. None of the subjects had systemic diseases or had undergone drug therapy in the previous 12 months. Eleven patients underwent the BAOSFE procedure with the simultaneous placement of 13 Brånemark Ti- Unite implants(Nobel Biocare, Sweden). The other 11 patients underwent the BAOSFE procedure with the simultaneous placement of 18 ITI SLA implants(Institut Straumann AG, Switzerland) (Table 1). There was no case of sinus membrane perforation during surgery.

2. Operative technique

On the initial examination, the patients'

Table 1. Distribution of Implant According to the Implant Systems (n=31)

Implant site (Tooth region)	*18*	*17*	*16*	*15*	*26*	*27*	*SUM*
Brånemark	0	2	3	1	3	4	13
ITI	2	3	6	2	3	2	18
SUM	2	5	9	3	6	6	31

medical histories were reviewed in order to rule out any local or systemic diseases that might contraindicate the surgical procedures. The patients received oral hygiene instructions and whole-mouth scaling prior to the surgery.

The BAOSFE procedure was performed using a Summers Osteotome kit†, as described by Summers[8,9]. Briefly, an incision was made under local anesthesia(Lidocaine 2% with 1:80.000 epinephrine¶) at the edentulous area to be treated. After the crestal incision had been made, full thickness buccal and palatal flaps were reflected. The site preparation began using the Summers #1 and #2 osteotomes. When the bone was too dense for hand instrumentation, 2mm twist drilling was used to reach the cancellous bone. The drilling remained 1mm below the floor of the sinus. The preparation site was widened using #2 and #3 Summers osteotomes. No instrument penetrated the cavity of the sinus at any time. A prepared various bone mix, which acts as a shock absorber, was added to the preparation site with a carrier. Elevation of the maxillary sinus membrane was achieved using the #3 osteotome that was used previously to force the graft ahead of its tip to achieve the sinus floor up-fracture. At this stage, the integrity of the sinus membrane was confirmed by the Valsalva manuever. Finally, each patient received the Brånemark Ti-Unite implants or the ITI SLA implants into the osteotomy site. The primary stability was achieved in all implants. Primary closure was achieved by using monofilament* suture material.

Postoperatively, the patients were instructed to rinse their mouth twice a day with a 0.12% chlorhexidine solution‡ during the first 2 weeks after surgery. Antibiotic regimens were prescribed for 7 days, and the sutures were removed after 10 days.

3. Prosthetic procedures

After a mean healing period of 9 months for the Brånemark implants and 8 months for the ITI implants, all the patients were rehabilitated with fixed crown or bridges.

4. Follow-up

After inserting the implants, the patients were followed-up 1 and 2 weeks, 3, 6, 9 and 12 months. A radiological evaluation was performed using minimum of three panoramic radiographs according to the following schedule: prior to surgery, immediately after surgery, and 6 months after surgery(Figure 1).

5. Analysis of radiographs

Using a scanner, the panoramic radiographs were digitalized. The Digital image analysis program# was used for the linear analysis of the panoramic radiographs. The magnification of panoramic radiograph was corrected using the known actual length of the inserted implants and an accurate graft height could be obtained. This was undertaken by one investigator. The radiographs from the same patient were blinded to the time. The following radiographic parameters from each radiograph were measured(Fig.2):

Table 2. Native Bone Height and Implant Distribution

Preoperative height	*Brånemark*	*ITI*	*SUM*
4 mm or less	0	9	9
4 to 5 mm	2	2	4
5 mm or greater	11	6	17
SUM	13	17	30

- ▶ The native bone height : the distance from the alveolar crest to the floor of the maxillary sinus at the implant site, which is represented as a mean of the mesial and distal native bone heights.
- ▶ The grafted bone height: the distance from the floor of the maxillary sinus to the border of the grafted bone at the implant site, which is represented as a mean of mesial and distal grafted bone height.
- ▶ The implant height: the distance from the apex to the head of the fixture.

6. Statistical analysis

The survival rate of each implant system was calculated. A paired t-test was used to calculate the statistical differences of the changes in the grafted bone height during the observation period within the each implant system. Unpaired t-test was used to calculate the statistical differences in grafted bone height change between the two implant systems. A P value < 0.05 was considered to be significant.

Ⅲ. Results

Clinical and radiographic healing was uneventful during the observation periods of 12 months. Table 1 shows the distribution of the implants. The 31 osseointegrated implants represent a survival rate of 96.8%. The Brånemark Ti-Unite surface implants showed 100%(13/13) survival rate and the ITI SLA surface implants showed 94.4% (17/18) survival rate. One of the 18 ITI implants was lost during the observation period. A lateral force or overload induced by the temporary denture after placing the implant might be responsible for the failure. The native bone height of the Brånemark Ti-Unite surface implant was significantly larger than that of the ITI SLA surface implant(Table 2). The patients' details are documented in tables 3 and 4 according to the implant systems.

¶ 2% lidocaine, 1:100,000 epinephrine, Kwangmyung Pharm., Seoul, Korea
† 3i, Implant Innovations, Palm Beach Garden, FL, USA
* Ethilon, Ethicon, Johnson & Johnson Int., Edinburgh, UK
‡ Hexamedin, Bukwang Pharmaceutical Co., Korea.
§ HP scanjet 7400c , Hewlett Packard, USA
\# Image-Pro Plus®, Media Cybernetics, Silver Spring, M.D., USA

The gain in the grafted bone height of the Brånemark Ti-Unite implants was 6.63mm ranging from 3.78mm to 11.09mm, and that of the ITI SLA implants was 7.72mm, ranging from 4.24mm to 9.87mm. A statistically significant difference between the pre-surgical and post-surgical bone height existed in both implant systems($P<0.05$). However, there was no significant difference in the gain of the grafted bone height between the implant systems.

The total mean reduction in the grafted bone height was 0.6mm(9.29%) of the grafted bone 6 months after surgery. There was a statistically significant reduction in the grafted bone height between that observed immediately after surgery and 6 months after surgery($p<0.05$). The mean reduction in the grafted bone height of the Brånemark Ti-Unite implants was 0.67mm(10.73%) ranging from -0.99mm to 3.34mm. Regarding the ITI SLA implants, the mean reduction in the grafted bone height was 0.55mm(8.18%) ranging from -0.61mm to 2.26mm(Table 4). However, there was no statistically significant difference between the two systems.

Table 3. Native, Grafted bone height and Reduction of the grafted bone height of the Brånemark Ti-Unite System

Patient No.	Site (Tooth region)	Implant D (mm)	Implant L (mm)	NBH (mm)	GBH_0 (mm)	GBH_6 (mm)	Reduction (mm)	Reduction (%)
1	16	4	11.5	9.91	6.49	5.81	0.68	10.45
	15	4	13	11.44	4.25	4.51	-0.26	-6.15
2	26	5	8.5	7.45	3.78	2.55	1.23	32.44
3	16	5	10	5.73	7.89	7.71	0.18	2.23
4	26	5	8.5	5.82	5.30	5.29	0.01	0.22
	27	4	8.5	4.68	5.64	4.12	1.52	26.97
5	16	5	10	5.58	7.26	3.92	3.34	46.05
6	27	5	11.5	6.21	11.09	10.46	0.63	5.71
7	27	5	10	5.39	6.85	7.00	-0.15	-2.23
8	17	4	11.5	7.82	7.68	6.87	0.81	10.56
9	26	5	8.5	5.00	7.13	8.12	-0.99	-13.93
10	27	4	11.5	8.71	5.91	5.07	0.84	14.27
11	17	5	10	6.34	6.98	6.08	0.90	12.97
Average				6.93	6.63	5.96	0.67	10.73
Range (MIN.)				4.68	3.78	4.77	-0.99	-13.93
(MAX.)				11.44	11.09	7.75	3.34	46.05

D : Distal
M : Mesial
NBH : Native bone height
GBH0 : Grafted bone height(Baseline)
GBH6 : Grafted bone height(6 Months)
MIN : Minimum
MAX : Maximum

Table 4. Native, Grafted bone height and Reduction of the bone height of the ITI SLA System

Patient No.	Site (Tooth region)	Implant D(mm)	Implant L(mm)	NBH (mm)	GBH_0 (mm)	GBH_6 (mm)	Reduction (mm)	Reduction (%)
1	15	4.1	10	8.07	4.24	3.03	1.21	28.46
	16	4.8	12	8.17	4.92	3.57	1.35	27.54
2	26	4.1	14	5.32	7.77	8.12	-0.35	-4.47
3	17	4.8	10	5.00	7.67	5.41	2.26	29.40
4	27	4.1	10	3.60	8.64	8.43	0.21	2.41
5	15	4.1	10	3.12	9.87	10.48	-0.61	-6.17
	16	4.8	10	4.11	9.04	8.76	0.28	3.10
6	16	4.1	10	2.83	9.43	7.19	2.24	23.73
7	18	4.1	10	3.98	7.95	7.64	0.31	0.04
8	16	4.1	10	2.84	8.98	8.21	0.77	8.55
	17	4.1	10	2.10	9.15	8.70	0.45	4.91
	18	4.1	10	3.71	6.86	5.96	0.90	13.08
9	16	4.8	10	5.37	4.74	4.20	0.54	11.35
10	16	4.1	10	5.25	6.53	6.50	0.03	0.44
	17	4.1	10	3.40	8.15	8.56	-0.41	-5.06
11	26	4.1	10	3.95	8.74	9.11	-0.37	-4.27
	27	4.8	10	6.63	8.52	8.00	0.52	6.09
Average				4.56	7.72	7.17	0.55	8.18
Range (MIN.)				2.83	4.24	4.85	-0.61	-6.17
(MAX.)				8.17	9.87	7.61	2.26	29.40

D : Distal
M : Mesial
NBH : Native bone height
GBH_0 : Grafted bone height (Baseline)
GBH_6 : Grafted bone height (6 Months)
MIN : Minimum
MAX : Maximum

Ⅳ. Discussion

The aim of this study was to evaluate and compare the clinical results of the Brånemark Ti-Unite and ITI SLA implants placed simultaneously using BAOSFE procedure, and to assess the change in the graft height radiographically in these two different implant systems after the BAOSFE procedure during the initial healing period. The results indicated that the simultaneous placement of the Brånemark Ti-Unite as well as the ITI SLA implant using the BAOSFE procedure is a feasible treatment option for patients with atrophic posterior maxilla. In addition, radiographic reduction of the grafted bone height was found during the initial healing period of 6 months in similar pattern at these two different implant systems.

Although there were various results with

different follow-up periods, inclusion criteria, surgical and prosthetic techniques, and other factors, the BAOSFE procedure with the simultaneous placement of an implant showed a predictable survival rate ranging from 95% to 100%[6,10,11]. The 1-step approach to the atrophic posterior maxilla using the BAOSFE procedure has the advantages of being less invasive. This technique can also enhance the bone quality of the implant site from type III or IV to type II. Reduction of surgical and healing time can be achieved because a coordinated consolidation of the graft around the implants during the healing period is expected. Moreover, there has been little difference reported between the survival rate of the implants placed immediately at the time of the grafting or those placed after a delay[19]. It has been reported that the differences in the implant designs and surface characteristics may influence the survival rate of the different types of implants. Regarding the extent of bone retention, some studies have reported that the SLA surface is superior to the machined surface implant[20,21]. Moreover, it was reported that the survival rate of the SLA surfaced implants in the sinus-augmented maxilla was significantly higher than that of the machined surface implants[22].

It was reported that the survival rate of the implants was also influenced by the quality and quantity of the native bone [11,12,23]. In particular, the survival rate is markedly reduced when the native bone height in a implant site was 4mm or less[11] because it is difficult to achieve primary stability of the implant, and there is a higher possibility of the Schneiderian membrane tearing[24]. Therefore, at least 5mm of the native bone was recommended for the 1 step approach. In this study, the mean height of the native bone was 5.58mm with a distribution of 6.93mm for the Brånemark and 4.56mm for the ITI SLA implant. Thirteen of 30(43%) sites were < 5mm in the native bone height and 9 out of ITI SLA implant were 4mm or less. Nevertheless, a predictable high survival rate could be obtained at both implant systems. Peleg et al.(1999) evaluated the efficacy of the augmentation of the maxillary sinus using the lateral approach with the simultaneous placement of hydroxyapatite surface implants in patients with 3 to 5 mm of the residual bone height [25]. All the 160 implants in the 63 patients were stable during 2 to 4 year follow-up periods. Together with previous studies, these results showed that the rough surface implants used in the augmented sinus area could provide a predictable prognosis. Therefore, a 1-step procedure of grafting the maxillary sinus and the simultaneous placement of rough surface implants might be selected as a feasible treatment option for patients with as little as 5mm of the native bone height.

The dimensional changes in the height of the graft augmented in the sinus have been documented. At the Sinus Consensus Conference of 1996, 100 patients, 145 sinus-grafting sites were evaluated using panoramic radiographs over a 3-year period. It was reported that all graft materials resulted in a radiographic reduction ranging from 0.79 to 2.09mm. However, it was not determined whether this reduction in the

graft height occurred in an initial healing period or was a part of an ongoing healing process. Hallman et al. analyzed 30 maxillary sinuses in 20 patients who were grafted with a mixture of autogenous bone and bovine hydroxyapatite, and reported that a small(<10%) but statistically significant dimensional reduction was observed 12 months after surgery and after 1 year of loading[26]. Other studies on the reduction of sinus grafts using X-rays were also available[27]. In this study, it was demonstrated that during the course of the initial healing periods of 6 months, the height of the grafted bone was reduced by an overall mean of 0.6mm (9.29%), which comprised of a mean of 0.67 mm(10.73%) for the Brånemark Ti-unite implants and 0.55mm(8.18%) for the ITI SLA implants. However, the difference between two implant systems was not statistically significant. Therefore, it appears that adimensional healing response of the grafted bone may occur with a similar pattern in the Brånemark Ti-Unite and the ITI SLA implants. The reduction of the grafted material was influenced more by the host healing response than by submergence or implant characteristics. The radiographic evaluations in this study could not fully characterize the nature of the graft materials in the sinus. A histological finding will be essential for assessing the healing event in augmented sinus. Longer follow-up periods will be also be needed to determine if the reduction observed in this study is an ongoing process or occurs only in the initial healing period. However, together with other studies, it can be concluded that a major volumetric reduction of the grafted materials in sinus occurs during initial healing period.

V. Conclusion

The simultaneous placement of the Brånemark Ti-Unite and ITI SLA implants with BAOSFE procedure showed predictable clinical results. In addition, radiographic reduction of the grafted bone height was found during the initial healing period of 6 months in similar pattern at these two different implant systems.

VI. References

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사진부도 설명

Figure 1a. Taking panoramic radiographs(Brånemark Ti-Unite implant)
(1) Prior to surgery (2) Immediately after surgery (3) 6 months after surgery

Figure 1b. Taking panoramic radiographs(ITI SLA implant)
(1) Prior to surgery (2) Immediately after surgery (3) 6 months after surgery

Figure 2. A - native bone height : the distance from the alveolar crest to the floor of the maxillary sinus at the implant site, which is represented as a mean of the mesial and distal native bone heights.
B, B′ - grafted bone height : the distance from the floor of the maxillary sinus to the border of the grafted bone at the implant site, which is represented as a mean of mesial (B) and distal (B′) grafted bone height.
C - the implant height: the distance from the apex to the head of the fixture TABLES

사진부도(I)

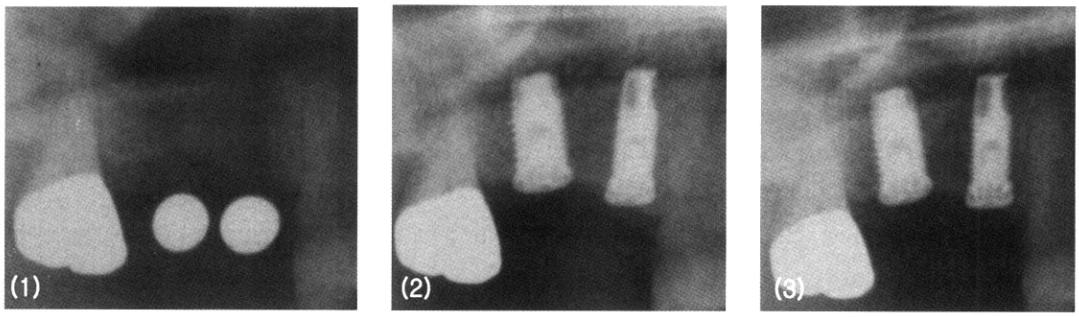

Figure 1a

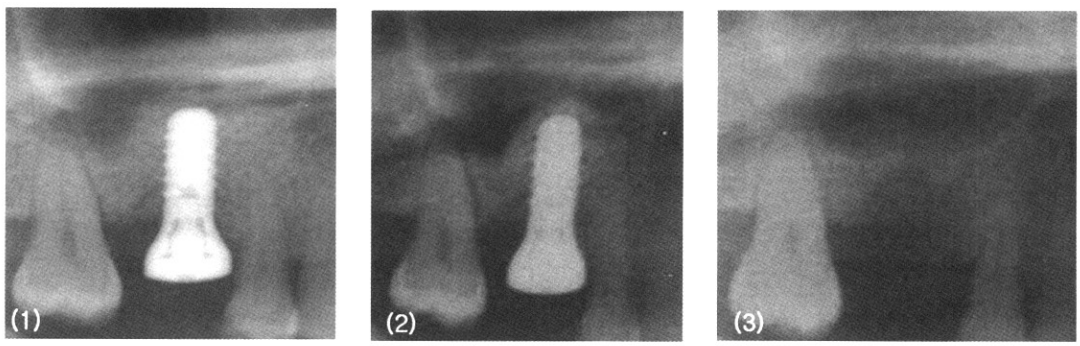

Figure 1b

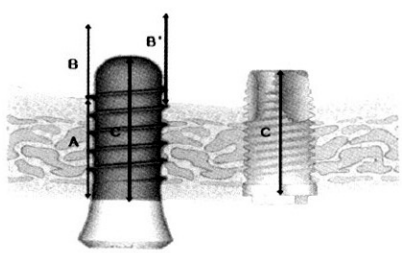

Figure 2

-Abstract-

Osteotome 상악동 거상술과 동시에 식립한 Brånemark Ti-Unite 과 ITI SLA임프란트의 비교 연구

강남원[1] · 정의원[1,2] · 최성호[1,2,3] · 조규성[1,2,3] · 채중규[1,2] · 김종관[1,2,3] · 김창성[1,2,3]

[1]연세대학교 치과대학 치주과학교실,
[2]연세대학교 치과대학 구강과학연구소
[3]BK21 의과학 사업단

1. 목적

Osteotome 상악동거상술(Bone Added Odteotome Sinus Floor Elevation ; 이하 BAOSFE) 과 동시에 식립한 임프란트(Brånemark, ITI)의 예상 생존율에 대해 현재까지 정확히 알려진 바는 없었으며, Brånemark Ti-Unite 과 ITI SLA 임프란트의 표면에 대한 비교 연구 또한없었다. 이번 연구는 BAOSFE 술식과 동시에 식립한 Brånemark Ti-Unite 과 ITI SLA 임프란트의 임상 결과를 비교, 평가하고 초기 치유기간 동안의 이식골 높이의 변화를 방사선학적으로 관찰하여 두 가지 임프란트 시스템을 비교해 보고자 한다.

2. 방법

위축된 상악 구치부를 갖는 22명의 환자를 대상으로, BAOSFE술식과동시에 Brånemark Ti-Unite(11명, 13 임프란트)임프란트와 ITI SLA(11명, 18 임프란트)임프란트를 식립하였다. 수술 전, 임프란트 식립 직후, 술후 6개월의 파노라마 방사선 사진을 촬영하여 비교 및 평가에 사용하였다. 각 임프란트 시스템의 생존율을 측정하고, 술전 상악동저 높이와 식립된 임프란트 길이를 참고하여 이식골 높이의 방사선학적 변화를 평가하였다.

3. 결과

평균12개월의 추적기간 결과, Brånemark Ti-Unite 임프란트의 생존율은 100%(13/13 임프란트)이었으며, ITI SLA 임프란트의 생존율은 94.4%(17/18 임프란트)이었다. 초기 치유 기간인 6개월 동안 평균 이식골 높이의 감소는 Brånemark Ti-Unite 임프란트에서 0.67mm(10.73%), ITI SLA 임프란트에서는 0.55mm(8.18%)로 나타났다. 두 가지 임프란트 시스템 간의 유의성 있는 차이는 보이지 않았다.

4. 고찰

BAOSFE 술식과 동시식립한 Brånemark Ti-Unite 과 ITI SLA 임프란트는 위축된 상악 구치부를 갖는 환자에서 효과적인 치료방법이 될 수 있으며, 임프란트 표면에 따른 이식골의 치유 반응은 두 가지 임프란트 시스템에서 유사한 양상으로 일어남을 알 수 있었다.

주요어 : 상악동, osteotome, 상악동 거상술, 임프란트, 방사선학, Brånemark 시스템 임프란트, ITI 시스템 임프란트, 이식골 변화 SLA 임프란트