Clinical and Radiographic Evaluation of Bone Added Osteotome Sinus Floor Elevation with Simultaneous Placement of Brånemark Ti-Unite and ITI SLA implants

Nam-Won Kang

The Graduate School

Yonsei University

Department of Dental Science

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This certifies that the dissertation thesis

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Thesis Supervisor : Chang-Sung Kim

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Seong-Ho Choi

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Kee-Deog Kim

The Graduate School

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감사의 글

3년간의 수련기간을 마치면서 치의학에 대한 약간의 지식과 함께 연구의 작은 결실인 석사학위를 받게 되었습니다.

제가 이 작은 결실을 맺을 수 있도록 부족한 저에게 마지막 순간까지 결정적인 조언과 지도를 아낌없이 해주신 김창성 교수님께 깊은 감사를 드립니다. 또한 수련기간 동안 항상 변함없는 관심을 보여주시고, 치과의사로서의 지식과 사회생활에 대한 많은 가르침을 주신 김종관 교수님, 채중규 교수님, 조규성 교수님, 최성호 선생님께 깊은 감사의 말씀을 전합니다. 본 연구에 많은 관심과 도움을 주신 김기덕 교수님께도 감사의 마음을 전합니다.

본 연구 내내 많은 관심과 격려를 아끼지 않은 윤정호 선생님, 정의원 선생님과 치주과 의국원 여러분께 진심으로 고마운 저의 마음을 전합니다.

마지막으로, 항상 변함없는 마음으로 저를 지지해 주시며, 늘 아낌없는 사랑으로 감싸주시고 헌신적인 도움을 주시는 사랑하는 저의 아버지, 어머니 그리고 동생들에게 진정으로 감사하는 마음을 담아 이 논문을 바칩니다.

모든 분께 진심으로 감사 드립니다.

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저자 씀

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Abstract

Clinical and Radiographic Evaluation of Bone Added Osteotome Sinus Floor Elevation with Simultaneous Placement of Brånemark Ti-Unite and ITI SLA implants

The predictable survival rates in a bone added osteotome sinus floor elevation (BAOSFE) procedure with the simultaneous placement of the Brånemark and the ITI implant have been well documented. The aim of this study was to evaluate the clinical results of the Brånemark Ti-Unite and ITI SLA implants placed simultaneously with the BAOSFE procedure, and to radiographically assess the change in the graft height in these two different implant systems after the BAOSFE procedure during the initial healing period.

Twenty two patients with an atrophic posterior maxilla received the BAOSFE procedure with simultaneous placement of either the Brånemark Ti-Unite (11 patients, 13 implants) or ITI SLA implants (11 patients, 18 implants). Minimum of three panoramic radiographs were taken from each patient. A panoramic radiograph was taken before surgery, immediately after the placement of the implants, and 6 months after the surgery. The survival rate according to the two implant systems was determined. The radiographic changes in the graft height were also calculated with respect

to the implant with a known length and original sinus height.

The implant survival rate was 100% (13/13 implants) for the Brånemark Ti-Unite implants and 94.4% (17/18 implants) for the ITI SLA implants after a mean follow-up period of 12 months. During the initial healing period of 6 months, the mean reduction of the grafted bone height occurred 0.67mm (10.73%) at the Brånemark Ti-Unite implants and 0.55mm (8.18%) at the ITI SLA implants. The difference between the two implant systems was not statistically significant.

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, it appears that a dimensional healing response of the grafted bone may occur in a similar pattern between these different implant systems.

Key words : maxillary sinus, osteotome, sinus lifting, implant, panoramic radiography, Brånemark system implant, ITI system implant, graft change

Clinical and Radiographic Evaluation of Bone Added Osteotome Sinus Floor Elevation with Simultaneous Placement of Brånemark Ti-Unite and ITI SLA implants

Nam-Won Kang, D.D.S.
Department of Dental Science, Graduate School,
Yonsei University
(Directed by Prof. Chang-Sung Kim, D.D.S., M.S.D., PhD.)

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 (Jenson et al. 1990; Adell et al. 1990), Le Fort I osteotomies with an interpositional bone graft (Isaksson 1994; Kahnberg 1989), lateral approach sinus augmentation (Fugazzotto et al. 1994, 1998; Blomqvist et al. 1998) and osteotome sinus augmentation (Summers 1994; Zitzmann et al. 1998; Rosen et al. 1999). 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 (Summers 1994). Using the Summers osteotome kit (Summers 1994), 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 bone added osteotome sinus floor elevation (BAOSFE) procedure 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 (Zitzmann et al. 1998; Rosen et al. 1999; Bruschi et al. 1998; Winter et al. 2002; Horowitz 1997; Komarnyckyj et al. 1998).

Clinical and radiographic studies on the dimensional change in the grafted bone have also been reported (Buchmann et al. 1999; Raghoebar et al. 2001). It was reported that all the graft materials resulted in a radiographic reduction ranging from 0.79 to 2.09mm 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 the implants (Hatano et al. 2004). 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 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

A. 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. No patients showed signs and symptoms of sinus and intraoral disease. The patients 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 eleven patients underwent the BAOSFE procedure with the simultaneous placement of 18 ITI SLA implants (Institute Straumann AG, Switzerland) (Table 1). There was no case of sinus membrane perforation during surgery.

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

B. Operative technique

On the initial examination, the patients' 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 ki t*, as described by Summers (Summers 1994). Briefly, an incision was made under local anesthesia (Lidocaine 2% with 1:100,000 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

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* 3i, Implant Innovations, Palm Beach Garden, FL, USA
†2% Lidocaine, 1:100,000 epinephrine, Kwangmyung Pharm., Seoul, Korea

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.

C. 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.

D. Follow-up

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

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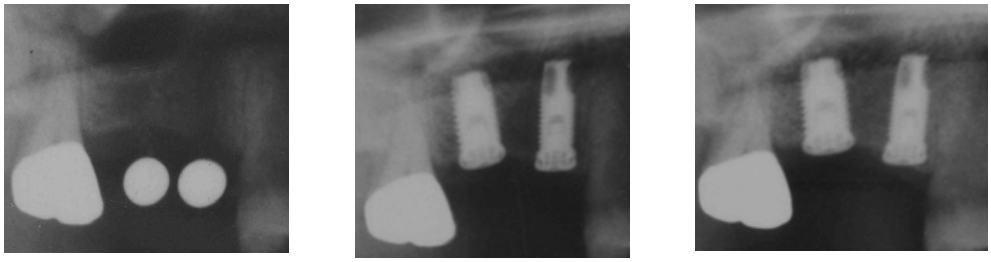
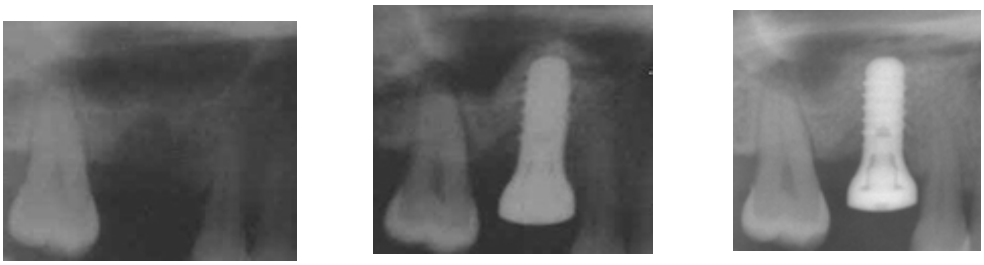
‡Ethilon, Ethicon, Johnson & Johnson Int., Edinburgh, UK
§ Hexamedin, Bukwang Pharmaceutical Co., Korea



Prior to surgery Immediately after surgery 6 months after surgery

Figure-1a Taking panoramic radiographs (Brånemark Ti-Unite implant)



Prior to surgery Immediately after surgery 6 months after surgery

Figure-1b Taking panoramic radiographs (ITI SLA implant)

E. 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

** HP scanjet 7400c, Hewlett Packard, USA
††Image-Pro Plus®, Media Cybernetics, Silver Spring, M.D., USA

corrected using the known actual length of the inserted implants and an accurate graft height could be obtained. This was undertaken by a one investigator. The radiographs from the same patient were blinded to the time. The following radiographic parameters from each radiograph were measured (Fig. 2).

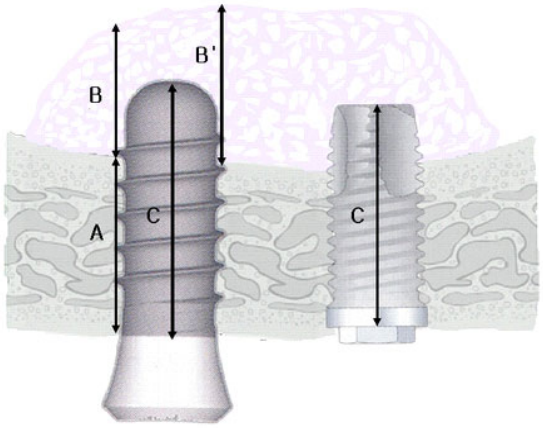


Figure-2

A - 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.

B, B' - 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 (B) and distal (B') grafted bone height.

C - the implant height ; the distance from the apex to the head of the fixture.

F. 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 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 overlord 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.

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

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

Patient No.	Site (Tooth)	Implant D(mm)	Implant L(mm)	Graft Type	NBH (mm)	GBH_0 (mm)	GBH_6 (mm)	Reduction (mm)	Reduction (%)
1	16	4	11.5	P+A	9.91	6.49	5.81	0.68	10.45
	15	4	13	P+A	11.44	4.25	4.51	-0.26	-6.15
2	26	5	8.5	P+A	7.45	3.78	2.55	1.23	32.44
3	16	5	10	P	5.73	7.89	7.71	0.18	2.23
4	26	5	8.5	P+A	5.82	5.30	5.29	0.01	0.22
	27	4	8.5	P+A	4.68	5.64	4.12	1.52	26.97
5	16	5	10	P	5.58	7.26	3.92	3.34	46.05
6	27	5	11.5	H	6.21	11.09	10.46	0.63	5.71
7	27	5	10	P	5.39	6.85	7.00	-0.15	-2.23
8	17	4	11.5	P	7.82	7.68	6.87	0.81	10.56
9	26	5	8.5	P+A	5.00	7.13	8.12	-0.99	-13.93
10	27	4	11.5	X	8.71	5.91	5.07	0.84	14.27
11	17	5	10	P+A	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 : Diameter

L : Length

NBH : Native bone height

GBH_0 : Grafted bone height (Baseline)

GBH_6 : Grafted bone height (6 Months)

MIN : Minimum

MAX : Maximum

P : Alloplast, A : Allograft, X : Xenograft

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

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

L : Length

NBH : Native bone height

GBH_0 : Grafted bone height (Baseline)

GBH_6 : Grafted bone height (6 Months)

MIN : Minimum

MAX : Maximum

P : Alloplast, A : Allograft, X : Xenograft

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.

IV. Discussion

The aim of this study was to evaluate 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% (Fugazzotto 1998, Zitzmann et al. 1998, Rosen et al. 1999). 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. Reducing the 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 (Tong et al. 1998). 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 machine surfaced implant (Wennerberg et al. 1996, Ogawa et al. 2000). 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 surfaced implants (Pinholt 2003).

It was reported that the survival rate of the implants was also influenced by the quality and quantity of the native bone (Rosen et al. 1999, Bruschi et al. 1998, Cavicchia et al. 2001). In particular, the survival rate is markedly reduced when the native bone height in a implant site was 4mm or less (Rosen et al. 1999) because it is difficult to achieve the primary stability of the implant, and there is a higher possibility of the Schneiderian membrane tearing (Fugazzotto 2003). 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 (Peleg et al. 1999). All the 160 implants in the 63 patients were stable during the 2

to 4 years 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 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 (Hallman et al. 2002). Other studies on the reduction of sinus grafts using X-rays were also available (Nicolaas et al. 2001). 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 0.67mm (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 a dimensional 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 significant 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.

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국문 요약

골첨가 상악동저 거상술과 동시에 식립된 Brånemark Ti-Unite와 ITI SLA 임플란트의 임상적, 방사선학적 분석

연세대학교 대학원 치의학과

(지도 김 창 성 교수)

강 남 원

골첨가 상악동저 거상술(BAOSFE)과 동시에 이루어지는 Brånemark Ti-Unite, ITI SLA 임플란트 식립의 예측가능한 생존률은 잘 보고되어 있다. 이 연구의 목적은 BAOSFE 술식과 동시에 식립된 Brånemark Ti-Unite, ITI SLA 임플란트의 임상결과를 평가하고, 아울러 BAOSFE 후 초기 치유 기간동안의 이식재 높이 변화를 방사선학적으로 측정하는 것이다.

위축된 상악 구치부를 가진 총 22명의 환자에서 BAOSFE 술식과 함께 Brånemark Ti-Unite (11명, 13개의 임플란트) 혹은 ITI SLA (11명, 18개의 임플란트) 임플란트가 식립되었다. 각 환자별로 최소한 3번의 파노라마 방사선사진이 촬영되었다. 파노라마 방사선사진은 술전, 임플란트 식립 직후, 술후 6개월에 촬영되었다. 두가지 임플란트 시스템의 생존률을 계산하였다. 임플란트 길이와 초기 상악동 높이를 고려하여 이식재의 방사선학적 변화를 계산하였다.

평균 12개월의 추적검사 결과, Brånemark Ti-Unite 임플란트의 생존률은 100% (13/13), ITI SLA 임플란트의 생존률은 94.4% (17/18)이었다. 6개월의 초기 치유기간동안 이식재의 높이 감소량은 Brånemark Ti-Unite 임플란트군에서 0.67mm (10.73%), ITI SLA 임플란트군에서 0.55mm (8.18%)이었다. 두 임플란트 시스템사이의 이식재 변화량에 있어서 통계적으로 유의차가 없었다.

이 연구결과, 상악 구치부가 위축된 환자들에게 BAOSFE 술식과 함께 실시되는 ITI SLA, Brånemark Ti-Unite 임플란트 식립술은 적용 가능한 치료방법이다. 이식재의 치유반응은 두 가지 임플란트 시스템에서 비슷한 형태로 나타난다.

핵심되는 말: 상악동, 오스테오톰, 상악동저 거상술, 임플란트, 파노라마 방사선 사진, Brånemark 시스템 임플란트, ITI 시스템 임플란트, 이식재 변화