Maxillary Sinus Floor Augmentation Using a β-Tricalcium Phosphate (Cerasorb) Alone Compared to Autogenous Bone Grafts

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Purpose: *A prospective human clinical study was conducted to determine the clinical and histologic bone formation ability of 2 graft materials, a β-tricalcium phosphate (Cerasorb; Curasan, Kleinostheim, Germany) and autogenous chin bone, in maxillary sinus floor elevation surgery.* ***Materials and Methods:*** *Ten healthy patients underwent a bilateral (n = 6) or unilateral (n = 4) maxillary sinus floor elevation procedure under local anesthesia. In each case, residual posterior maxillary bone height was between 4 and 8 mm. In cases of bilateral sinus floor elevation, the original bone was augmented with a split-mouth design with 100% β-tricalcium phosphate on the test side and 100% chin bone on the contralateral control side. The unilateral cases were augmented with 100% β-tricalcium phosphate. After a healing period of 6 months, ITI full body screw-type implants (Straumann, Waldenburg, Switzerland) were placed. At the time of implant surgery, biopsy samples were removed with a 3.5-mm trephine drill.* ***Results:*** *Sixteen sinus floor elevations were performed. Forty-one implants were placed, 26 on the test side and 15 on the control side. The clinical characteristics at the time of implantation differed, especially regarding clinical appearance and drilling resistance. The increase in height was examined radiographically prior to implantation and was found to be sufficient in all cases. After a mean of nearly 1 year of follow-up, no implant losses or failures had occurred.* ***Discussion:*** *The promising clinical results of the present study and the lack of implant failures are probably mainly the result of requiring an original bone height of at least 4 mm at the implant location.* ***Conclusion:*** *Although autogenous bone grafting is still the gold standard, according to the clinical results, the preimplantation sinus floor elevation procedure used, which involved a limited volume of β-tricalcium phosphate, appeared to be a clinically reliable procedure in this patient population.* Int J Oral Maxillofac Implants 2005;20:432–440

Key words: *autogenous bone grafts, β-tricalcium phosphate, bone substitutes, sinus floor augmentation*

Lack of vertical ridge bone dimension in the posterior maxilla frequently precludes proper implant placement in this region. Increasing the absolute vertical bone height can be achieved by internal augmentation of the maxillary sinus floor. Sinus floor elevation was first described by Boyne and James[1] and later by Tatum.[2] The space created between the maxillary alveolar process, the elevated schneiderian membrane, and the rotated lateral sinus wall is filled with a graft material.

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Autogenous bone is considered the gold standard in grafting procedures.[3] However, donor site morbidity cannot be ignored, and sometimes only limited amounts of autogenous bone are available for harvesting.[4] These disadvantages have led to a continuous search for a suitable bone substitute. A variety of grafting materials for sinus augmentation have been used and reported on in the literature.[3,5–13] In the last few years, the authors have studied an allograft (demineralized freeze-dried bone), a bone morphogenetic protein (BMP) -7 (OP-1), and autogenous bone (iliac crest) as grafting materials for sinus floor elevation.[3,5,8,9] Of these grafting materials, autogenous bone has shown the best and most predictable results. Demineralized freeze-dried bone has demonstrated its capability as an osteoconductor.[8] A pilot study on BMP-7 (OP-1) indicated that this grafting material has osteoinductive potential, but the behavior of this material is insufficiently predictable for this indication area.[3,5,8]

The ultimate bone substitute should eventually be resorbed and replaced by new bone formation, thus permanently replenishing the defect or loss of bone. The authors have therefore chosen to study a pure-phase β-tricalcium phosphate (β-TCP), Cerasorb (Curasan, Kleinostheim, Germany), for sinus grafting. This alloplast is a derivate of hydroxyapatite, which is the mineral or inorganic component of bone. This in contrast with, for example, an allograft such as demineralized freeze-dried bone. Hydroxyapatite is nonresorbable and acts as a scaffold for osteoconduction. In animal studies, however, pure-phase β-TCP has been shown to be almost completely resorbable and simultaneously capable of new bone formation.[11,14–17] Thus, it could be considered a temporary bone replacement. Because it lacks growth factors, it has no osteoinductive properties; however, it does have osteoconductive properties.

The objective of this study was to determine the ability of this β-TCP to facilitate bone formation in comparison to autogenous bone grafts in the maxillary sinus.

MATERIALS AND METHODS

Patient Selection

The selected patients were either edentulous or partially edentulous in the posterior maxilla and required implant placement. Because of inadequate alveolar bone height for implant placement in the posterior maxilla, they were scheduled for a unilateral or bilateral 2-stage maxillary sinus floor elevation surgical procedure.

Patients ranged in age from 18 to 70 years. They were excluded if they:

- Had an American Society of Anesthesiologists (ASA) classification of 3 or 4
- Abused drugs (including alcohol)
- Had any systemic disease (eg, diabetes, immunosuppressive chemotherapy, rheumatoid arthritis, or other autoimmune diseases)
- Were pregnant
- Had a history of chronic paranasal sinus inflammation

Patients who were smokers were required to stop smoking 3 months prior to the first surgery and agreed not to smoke for the duration of the study.

A specific inclusion criterion was that the vertical dimension of the native maxilla be less than 8 mm but greater than 4 mm, so that the original bone height was adequate to provide primary stability and, later, integration of the implant. The native maxilla bone also had to have an adequate transverse dimension; patients who needed additional onlay bone grafting were excluded. All patients gave informed consent to the protocol, which was approved by the medical ethics committee of the university hospital.

Patients were divided into 2 groups, those requiring bilateral sinus floor elevation and those requiring unilateral sinus floor elevation. A healing period of 24 weeks was planned for both groups. The bilateral group was augmented according to a split-mouth design, with 100% β-TCP on the test side and 100% autogenous chin bone on the control side. The β-TCP had a particle size of 1,000 to 2,000 μm, which is the largest size available.

Presurgery

At the initial visit, an orthopantomogram of each patient was obtained to determine the vertical bone height at the planned implant location. The radiographic vertical height at the implant site was additionally assessed more accurately on coronal and axial computerized tomographic (CT) scans (slice thickness of 3 mm). Shortly before implant placement, additional CT scans were made in axial and coronal directions to evaluate the acquired bone fill.

At the time of implant placement, bone biopsies were obtained for histology and histomorphometric analysis with a 3.5-mm diameter trephine bur (Straumann, Waldenburg, Switzerland) at the dental implant sites. For labeling of the mineralizing surfaces, all patients received 1,000 mg tetracycline per day for 2 days, 3 weeks before bone biopsy specimen harvest (implant placement) and again 1 week before harvest. Furthermore, 1 lateral biopsy was taken from each posterior aspect of the maxilla, approximately 2 mm below the roof of the horizontally placed "trap door." The vertical and lateral biopsies were used for bone histology and histomorphometric analysis. In all cases, ITI full body screw-type (4.1-mm-diameter) dental implants (Straumann) were placed into the implant bed. Approximately 16 weeks later, the referring general practitioner began prosthodontic treatment.

As a prophylactic measure, at the time of sinus floor augmentation and at implant placement, patients received 1,000 mg amoxicillin 1 hour preoperatively followed by 500 mg amoxicillin 3 times a day for 7 days. For both procedures, patients received chlorhexidine 0.2% twice daily as antiseptic therapy for 2 weeks. For pain, 600 mg ibuprofen, a nonsteroidal anti-inflammatory drug, was prescribed.

Table 1 Clinical Results for 10 Patients (16 Sinus Floor Elevations)

Patients	Bilateral/ unilateral	M/F	Age	Operation time (grafting)	Perforation	β-TCP (g)	Healing time (mo)	Implants (test/ control)	Operation time (implant placement)	Postoperative infection	Follow-up (wk)
1	bi	M	59	120	Yes (chin)	3	26	3/3	90	No	77
2	bi	F	54	120	Yes (both sides)	1.5	26	3/2	60	No	56
3	bi	M	61	90	No	2	22	3/3	55	No	38
4	bi	F	51	130	Yes (chin)	1.5	25	2/2	50	No	45
5	bi	M	50	125	Yes (chin)	2	23	2/2	65	No	32
6	bi	F	48	105	No	1.5	32	3/3	80	No	21
7	uni	M	56	40	No	1	25	3	45	No	54
8	uni	M	50	45	No	1.5	24	3	45	No	46
9	uni	M	28	75	No	2.5	27	1	45	No	58
10	uni	F	65	85	Yes (β-TCP)	2	24	3	50	No	74
Mean			52.2	115 (bi)/ 62 (uni)		1.8	25.4	26/15	66 (bi)/ 62 (uni)		50.1

Sinus Elevation Surgery

The sinus grafting procedure followed Tatum's classical description.[2] The elevated "trap door" was rotated inward and upward along the upper horizontal axis into a horizontal position. The space created between the maxillary alveolar process and the newly created sinus floor was filled with either autogenous bone (chin bone) or β-TCP, according to the protocol. The β-TCP was mixed with venous blood to make it more sticky. No membrane was used to cover the lateral wall. Complete closure was performed with Gore-Tex sutures (W. L. Gore & Associates, Newark, DE), which were removed after 2 weeks.

Chin Graft Harvest Technique

The chin bone graft was harvested in cylinder form with an ITI explantation bur (inner diameter 4.2 mm; Straumann). In this manner, limited amounts of monocortical cortico-spongeous chin bone were obtained. The chin bone was harvested at least 5 mm inferior to the apices of the mandibular incisors and 5 mm superior to the inferior border of the mandibular bone. Wound closure was performed with resorbable sutures.

Implant Placement and Bone Biopsies

At the time of implant placement, bone biopsies were taken with a 3.5-mm-diameter trephine bur (Straumann) from the grafted areas at the dental implant positions. Also, 1 lateral biopsy was taken approximately 2 mm below the horizontal "trap door" in the grafted area. Additionally, several clinical parameters were assessed.[9] The endosseous implants (4.1-mm-diameter; Straumann) were placed, and wound closure was performed with nonresorbable Gore-Tex sutures, which were removed after 10 days.

Histology and Histomorphometry

The biopsy specimens were fixed overnight in 4% formaldehyde in phosphate buffer and transferred to 70% ethanol. The specimens were embedded in methylmetacrylate resin without decalcification. Sections 5 μm thick were made using a Jung K microtome (Reichert-Jung, Heidelberg, Germany) and stained with Goldner's trichrome method.

The histomorphometric measurements on the digitized images were processed using Leica QWin computer software (Leica Microsystems, Wetzlar, Germany). Sections stained with Goldner's trichrome were used to measure the total bone volume (BV), ie, the original or residual bone and the newly augmented bone, and total tissue volume (TV). The bone volume was calculated according to Parfitt and associates[18]: BV/TV × 100%. The statistical test used was the paired Student *t* test. Significance was accepted when $P < .05$. The data were presented as means and standard deviations.

Additionally, the osteoid volume, the resorption surface, and the mineral apposition rate were measured. All histomorphometric results have been published by Zerbo and colleagues.[19]

RESULTS

Clinical Results

During a 1-year period, 16 sinus floor elevations were performed in 10 patients, all treated in the outpatient clinic. The bilateral group consisted of 6 patients, while the unilateral group consisted of 4; related information is shown in Table 1.

Six perforations of the schneiderian membrane occurred. They were all covered with a resorbable demineralized freeze-dried laminar bone sheet (100

Table 2 Clinical Characteristics of the Grafted Area at the Time of Implant Placement

Characteristics	Test side (n = 10)	Control side (n = 6)
Continuity with native maxilla		
Yes	10	6
No	0	0
Strong recognizable demarcation to native bone		
Yes	2	6
Somewhat	6	0
No	2	0
Fibrous adhesions		
Yes	1	0
No	9	6
Drilling resistance (bone quality)		
Less resistance	9	0
Bone-like resistance	1	6
Purulent discharge		
Yes	0	0
No	10	6
Probing resistance		
Hard	1	6
Flexible	9	0
Soft	0	0
Cyst		
Yes	0	0
No	10	6

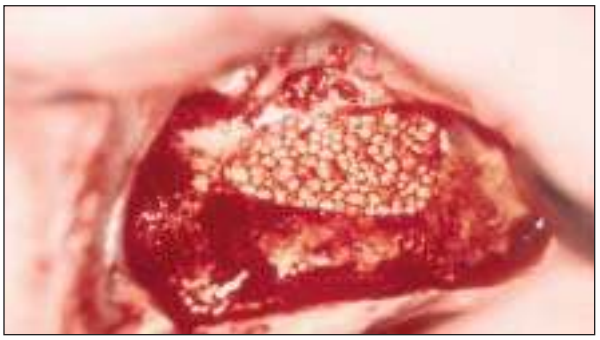

Fig 1a Sinus floor elevation with β-TCP alone.

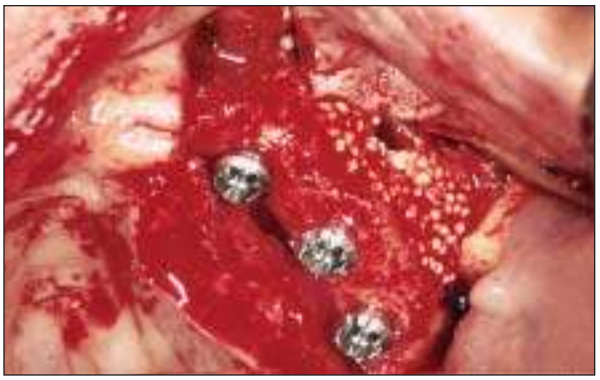

Fig 1b Same patient at time of implantation. Note that macroscopically, very little resorption of the original graft and sharp demarcation to the native maxilla could be seen.

to 300 μm thick; Ultimatics, Springdale, Arkansas; Pacific Coast Tissue Bank, Los Angeles, CA). A mean amount of 1.8 g β-TCP was used, which is just less than the contents of 1 container of Cerasorb (2 g). Only 2 patients needed more than 2 g of β-TCP. Postoperatively, there were no infections. The mean healing time was 25.4 weeks; in all cases, the healing was uneventful. Forty-one implants were placed, 26 on the Cerasorb side and 15 on the chin-bone control side. The mean follow-up was almost 1 year; no implants were lost.

After 6 months, at the time of implant placement, several clinical parameters were assessed (Table 2). At all test and control sites, good continuity of the grafted area to native maxilla was seen. In 2 patients, there was very little resorption of the β-TCP, and a sharp, macroscopic demarcation was formed between the original maxilla and the new bone (Figs 1a and 1b). Two patients showed almost no demarcation between the native maxilla and the new bone, and in the other 6 patients, the demarcation was moderate (Figs 2a and 2b). In 1 patient, a 2-mm fibrous adhesion lay over the entire grafted test site area and was fixed to the buccal mucoperiosteum (Figs 3a and 3b).

Radiographic Evaluation

The increase in height achieved by the sinus floor elevation procedure was measured from panoramic radiographs (Orthophos Plus DS Ceph; Sirona, Bensheim, Germany), taking the magnification (×1.25) into consideration. The preoperative bone height and bone height 6 months postsurgery were measured to the nearest 0.5 mm (Tables 3 and 4).

Coronal and axial preoperative CT scans were made as part of the presurgical evaluation. Six months after augmentation, shortly before implant placement, a second CT scan was made to evaluate the augmented area. In all cases (test and control) the material appeared to be well incorporated, with good continuity to the native maxilla (Figs 4a and 4b). Only 1 case showed evidence of pathology or mucosal cyst formation. In 1 case (a test site), a thickening of the maxillary mucosa was found without clinical symptoms. The β-TCP appeared very dense on the CT scans, so it was not necessary to measure the density of the grafted area in Hounsfield units.

In time, on subsequent orthopantomograms, there seemed to be a decrease in height and radiopacity at the β-TCP test sites, which is suggestive of resorption of the grafted area (Figs 5a to 5d).

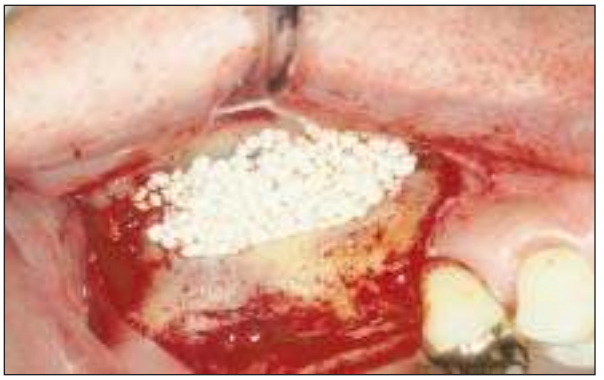

Fig 2a Sinus floor elevation with β-TCP alone.

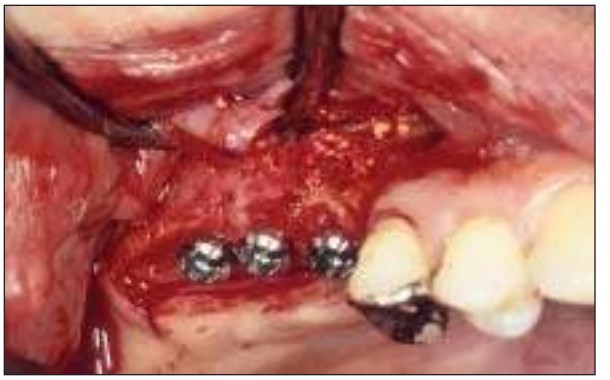

Fig 2b Same patient at time of implantation. Moderate changes of the original graft and less sharp demarcation to the native maxilla could be seen.

Fig 3a Sinus floor elevation with β-TCP alone.

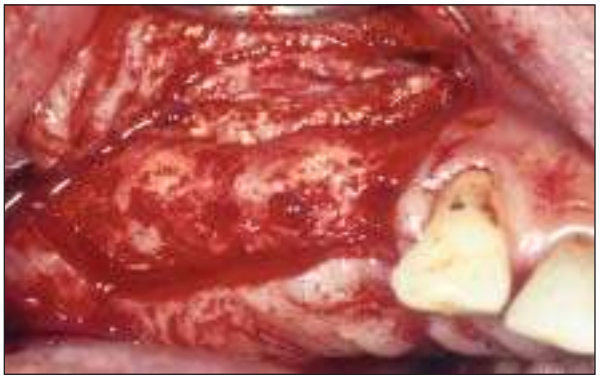

Fig 3b Same patient at time of implantation. A 2-mm-thick fibrous adhesion, which was excised before implant placement, lay over the entire grafted area.

Table 3 Bone Height Measured on an Orthopantomogram on the Test Side 6 Months After Grafting

Patient	Implant position	Bone height (mm)	
		Preoperative	Postoperative
1	12 (24)	8	15
	13 (25)	7	15
	14 (26)	4	15
2	4 (15)	8	14
	3 (16)	4	14
3	4 (15)	9	18
	3 (16)	7	17
4	13 (25)	4	14
5	13 (25)	6	13
	14 (26)	6	13
6	14 (26)	7	14
	15 (27)	7	14
7	3 (16)	7	13
	2 (17)	4	11
8	4 (15)	9	15
	3 (16)	6	14
	2 (17)	7	13
9	14 (26)	4	12
10	13 (25)	8	17
	14 (26)	7	16

Universal (FDI) tooth position shown. Data for 6 implants partially placed in the grafted area because of their location in the maxilla are not shown.

Table 4 Bone Height Measured on an Orthopantomogram on the Control Side 6 Months After Grafting

Patient	Implant position	Bone height (mm)	
		Preoperative	Postoperative
1	5 (14)	3	14
	3 (16)	4	13
2	13 (25)	6	15
3	13 (25)	8	16
	14 (26)	5	15
4	5 (14)	7	12
	4 (15)	1	11
5	4 (15)	6	13
	3 (16)	3	13
6	3 (16)	6	14
	2 (17)	6	15

Universal (FDI) tooth position shown. Data for implants partially placed in the grafted area because of their location in the maxilla are not shown.

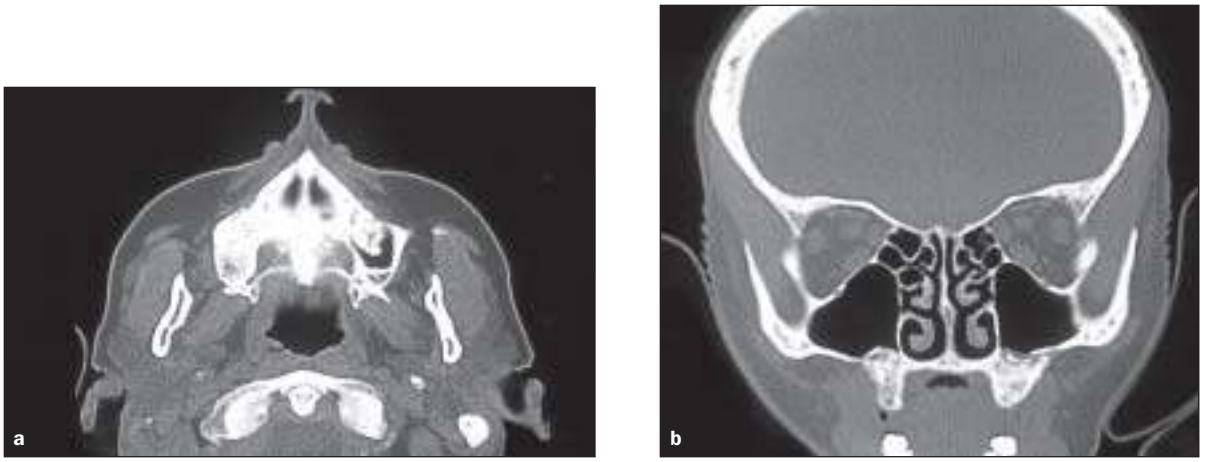

Fig 4 CT scans in coronal *(a)* and axial *(b)* directions in a bilateral case, with autogenous chin bone at the left and β-TCP on the right, just before implantation. The inward rotated "trap door" can be seen on both sides.

Histologic and Histomorphometric Results

The residual and newly augmented bone on the control sides was predominantly lamellar bone. The residual bone on the test sides was similar in architecture to that observed on the control sides, and bone volume percentage was not significantly different ($P = .19$).

In the augmented area on the test sides, bone formation was evident in all biopsies, although it was very scarce in some cases. Bone formation on the test sides, which consisted mainly of woven bone, was most active in the area adjoining the maxillary host bone, which is indicative of osteoconduction (Fig 6). In this area the β-TCP particles were often partially or even completely replaced by bone.

The lateral biopsies were short and poor in quality and did not contribute much to the study. The average bone volume formed in the augmented sinus was 41% (range, 32% to 56%) on the control sides and 17% (range, 9% to 27%) on the test sides, a statistically significant difference ($P < .05$) (Table 5).

Concerning the osteoid volume percentage or active young bone formation, Zerbo and colleagues[19] found a significantly higher percentage on the test site. This can probably be explained by the ongoing osteoconduction in the Cerasorb graft, in contrast with the more resting phase of the autogenous bone graft (Table 6), which had settled down to a normal but slow remodeling process.[19]

DISCUSSION

In a review of the relevant literature on anorganic bone additives used in maxillary sinus floor elevation surgery, Merkx and colleagues[20] made a plea for systematic prospective clinical and experimental studies to assess bone additives to autogenous bone or composite grafts analyzed with an adequate histomorphometric technique. To date, only 1 study on β-TCP[11] meets the criteria described by Merkx and colleagues.

The clinical results of the present study of β-TCP as a single additive for sinus floor elevation are encouraging. However, as 1 of the inclusion criteria was an original bone height of 4 mm at the implant location, the implant results are not entirely indicative of the quality of the β-TCP, since the original bone height may account for the primary stability and later integration of the implants.

In contrast to a recently published study on this topic by Szabo and coworkers,[11] patients who needed an additional onlay graft with autogenous bone were excluded from the present study. In all 4 patients who participated in Szabo and associates' study, the maxilla was atrophic to the extent that the reconstruction included not only sinus grafting but also a buccal onlay graft from the iliac crest. Since no onlay grafts were applied in the present study, a better assessment of the clinical appearance of the tested β-TCP side at the time of implant placement could be made.

β-TCP is called a temporary bone replacement because it has been shown to be almost completely resorbable simultaneous with new bone formation.[14–17] In contrast to the findings of previous studies,[11,14–17] which indicated complete resorption of the β-TCP in time, in the present study, various amounts of remnants of the original graft material were found clinically and histologically in all patients (Table 2). In 2 patients, very little resorption of the β-TCP was observed macroscopically after 6 months.

In all patients, an adequate bone height in the grafted area was found clinically and radiographically at the time of implantation. The gain in vertical dimension was measured 6 months after sinus graft-

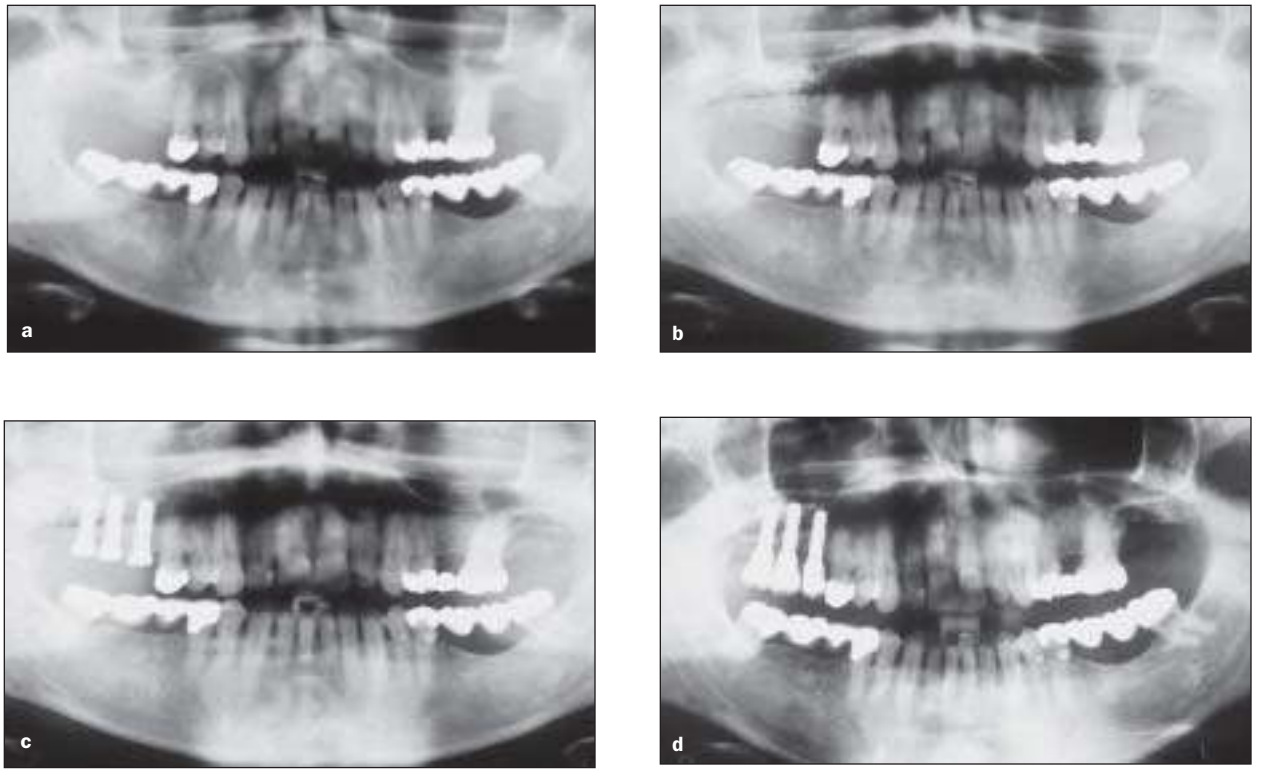

Fig 5 Orthopantomogram obtained *(a)* preoperatively, *(b)* after sinus floor elevation, *(c)* at the time of implantation (week 25), and *(d)* 1 year postoperatively. Over time, there appears to be a decrease in height and radiopacity on the test side.

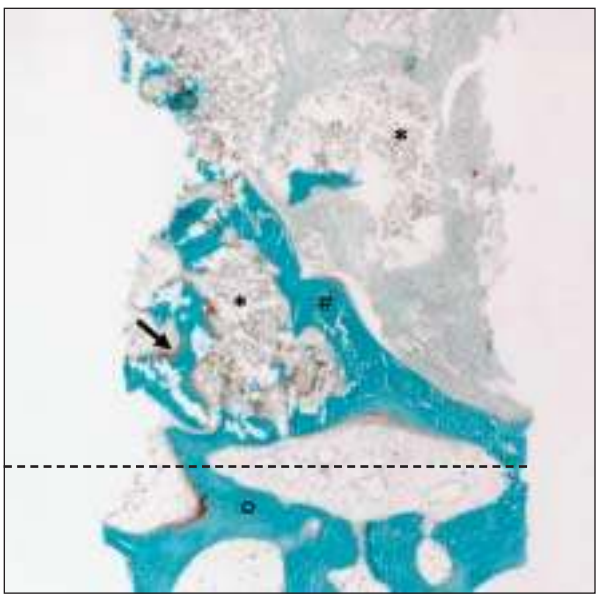

Fig 6 Bone core biopsy. Bone formation on the test side was most active in the area adjoining the maxillary host bone, which is indicative of osteoconduction. The dotted line separates the grafted area *(above)* from the original maxilla *(below)*. O = original maxilla; # = new bone formation; * = β-TCP particle; arrow indicates osteoid (Goldner's trichrome; original magnification × 20).

ing on an orthopantomogram. It is known that in panoramic radiography, the horizontal magnification may vary with head position. However, Tronje[21] stated that the image distortion in a panoramic radiograph that is exposed with the patient correctly positioned in the unit does not significantly affect the image of the object morphology. Despite the advantages of CT, the panoramic radiograph was regarded sufficient for the measurements in the present study. The authors decided not to obtain a third CT scan to avoid unnecessary radiation for the patient.

Histomorphometric analysis gives the most reliable results with regard to bone structure of the grafted area. Schultze-Mosgau and associates[22] investigated the histomorphometric and densitometric changes in bone volume and structure after avascular autogenous bone grafting in the extremely atrophic maxilla. The measured density of the grafted bone showed no correlation with the results of histomorphometric analysis of bone structure. In their opinion, computer-aided bone density measurements are not suitable for assessing bone structure. In the present study, the high density of Cerasorb, the β-TCP used in this study, which was measured on CT scan in Hounsfield units and compared to the histomorphometric analysis, had no predictive value with regard to bone structure.

Table 5 Bone Volume as a Percentage of the Total Tissue Volume of the New Bone on the Test Side

Patient	M/F	Age	Bone volume (%)	
			Residual bone	New bone
1	M	59	34	18
3	M	61	17	21
4	F	51	21	13
5	M	50	56	17
6	F	48	24	27
7	M	56	25	15
8	M	50	25	9
9	M	28	57	13
10	F	65	16	19
Mean			31 ± 14	17 ± 5

Data for patient 2 are not shown because of a problem in the processing of the biopsy sample.

Table 6 Bone Volume as a Percentage of the Total Tissue Volume of the New Bone on the Control Side

Patient	M/F	Age	Bone volume (%)	
			Residual bone	New bone
1	M	59	36	56
3	M	61	30	49
4	F	51	34	33
5	M	50	53	32
6	F	48	26	38
Mean			36 ± 10	41 ± 10

Data for patient 2 are not shown because of a problem in the processing of the biopsy sample.

The healing time of the graft was approximately 6 months; this result was similar to those reported by Szabo and colleagues[11] and Merkx and coworkers.[20] Because of the ongoing resorption of the autologous bone graft (control side), a prolonged healing time of the augmented sinuses in the split-mouth study design used was not desirable. In the search for an optimal healing time with regard to β-TCP, it would be of value to investigate a series of unilateral sinus floor elevations with a prolonged healing time.

No buccal membranes were used in the present study. Froum and colleagues[23] concluded that vital bone formation increased substantially when a nonresorbable membrane was placed over the lateral window. Further study concerning this matter should be performed. It would be of interest to determine whether the use of a resorbable buccal membrane in combination with β-TCP enhances bone regeneration. Froum and colleagues[23] also reported that vital bone formation increased substantially when intraoral autogenous bone was added to the xenograft OsteoGraf/N (Dentsply Friadent Ceramed, Lakewood, CO). Further studies should be undertaken to determine whether this effect would be seen with other graft materials, such as β-TCP. In 6 cases, the schneiderian membrane was perforated. In all 6 cases, the perforations were successfully covered with resorbable demineralized laminar bone membranes. In the case of perforation, even if the perforation appears to close or fall together after the bone lid and sinus mucosa lifting has been completed, a membrane should be used[8] to prevent small grains of β-TCP from leaking into the maxillary sinus. The perforations reported had no negative influence on the clinical results. In addition, a significantly longer operation time for the bilateral cases, both at the time of sinus floor elevation and at implantation, did not affect the clinical outcome.

From this study it would appear that β-TCP has osteoconductive properties when used in this indication. Zerbo and associates[19] suggested that the difference in bone volume between the test and control sides could be explained by difference between β-TCP and autogenous bone in regard to rate of osteoconduction; the process of osteoconduction was slower on the test side, whereas osteogenesis occurred faster on the autogenous bone control side. Since bone conduction is the dominating remodeling factor, the main impulse must come from the original denuded sinus floor, the nasal sinus wall, and the inward rotated door. It can be expected that the center of the graft would be last to be remodeled. The slower process of osteoconduction at the test side in relation to resorption of the β-TCP would probably be too long in cases with an original bone height of the native maxilla of less than 4 mm at the implant location.

In conclusion, although autogenous bone grafting is still the gold standard, the results of the present study showed that the sinus floor elevation procedure used in combination with a limited volume of β-TCP appears to be a reliable 2-phase procedure.

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