

# A 10-Year Clinical and Radiographic Study of Implants Placed after Maxillary Sinus Floor Augmentation with an 80:20 Mixture of Deproteinized Bovine Bone and Autogenous Bone

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[Correction made on 27 February 2013 after online publication: Deproteinized corrected to Deproteinezed in the title]

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## ABSTRACT

**Background:** There is a need for prospective, long-term follow-up studies of implants placed after maxillary sinus floor augmentation (MSFA).

**Purpose:** The aim of the present study was to determine whether deproteinized bovine bone (DPBB) used for MSFA may result in long-term stability of placed dental implants.

**Material and Methods:** Fourteen of the 20 patients included in the study were followed throughout the 10 years study period. These patients had 53 implants placed in 22 (6 unilateral and 8 bilateral) maxillary sinuses augmented with a mixture of 80% DPBB and 20% autogenous bone (80:20), and 15 implants placed in non-grafted sites. Clinical and radiographic examinations of the implants and grafts were performed.

**Results:** After 10 years of functional loading 15 of the initially placed 108 implants had been lost giving a cumulative survival rate of 86%. The mean marginal bone loss was  $1.6 \pm 1.0$  mm. There were no statistically significant differences in marginal bone level, pocket depth, or ISQ-values between implants placed in residual or grafted bone or between smokers or non-smokers at 10 years follow-up. There was a statistically significant reduction ( $p < .01$ ) in graft height between 3 months and 2 years but no further significant reduction up to 10 years.

**Conclusions:** The first 2 years after placement of implants with turned surfaces placed in sites after sinus floor augmentation with DPBB and autogenous bone seem to be critical for implant survival. At 10 years follow-up, the remaining implants presented excellent clinical and radiological results regardless of smoking habits or implant sites (augmented or residual bone).

**KEY WORDS:** clinical study, dental implants, deproteinized bovine bone, sinus floor augmentation

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DOI 10.1111/cid.12008

## INTRODUCTION

Pneumatized maxillary sinuses and resorption of the residual bone in the posterior maxilla after tooth extraction often requires augmentation procedures prior to implant treatment. Autogenous bone (AB) has been considered gold standard for sinus floor augmentation due to its osteoinductive and osteoconductive properties. However, the use of several other bone substitutes has been reported<sup>1–6</sup> as alternatives to autogenous bone. Recently, it has been suggested that deproteinized bovine bone (DPBB) and tricalcium phosphate (TCP) appear to be as effective as AB for augmentation of the maxillary sinus.<sup>7</sup> Nevertheless, prospective studies evaluating the long-term histological response

to DPBB after maxillary sinus floor augmentation (MSFA) are sparse<sup>8</sup> and the resorbability of DPBB has been discussed.<sup>8–13</sup> From a biological viewpoint, a slow resorption and degradation of a biomaterial is attractive. On the other hand a non-resorbable material may preserve the stability of the long-term bone volume and consequently maintain the osseous support for the implants.

The survival rates of implants placed in augmented maxillary sinuses seem to be decreased when implants with turned surfaces are used and in the absence of a membrane to cover the lateral window during the initial healing period.<sup>14</sup> In a recent systematic review of sinus floor augmentation procedures, the incidence of implant loss before functional loading was significantly higher for turned surface implants compared to moderately rough surface implants.<sup>15</sup> This review also demonstrated that longitudinal studies with observation periods of 10 years or more are completely lacking. In the present longitudinal study with an observation period of 10 years, clinical results of turned implants placed after sinus floor augmentation with DPBB and AB were evaluated. The aim of the present study was to determine whether DPBB used for MSFA may result in long-term stability of placed dental implants.

## MATERIALS AND METHODS

The patients and surgical techniques have also been described in previous studies.<sup>1,8</sup>

### Patients

Twenty consecutive patients (14 women and 6 men) with a mean age of 62 years, range 48–69, with severe, posterior atrophy of the alveolar process were included in this study. Two patients were edentulous, 8 patients had a bilateral loss of molars or premolars, and 10 patients had a unilateral loss of molars or premolars. Thirty maxillary sinuses that had less than 5 mm sub-antral alveolar bone (lowest part; mean, 1.6 mm; range 1–3 mm, highest part; mean 3.8 mm, range 2–5 mm) were treated with an augmentation of the sinus floor and delayed implant placement. Fourteen of the patients were followed up at 10 years (mean 10.2 years  $\pm$  0.4 years) of functional loading. All patients gave their informed consent and the study had been approved by the regional ethical review board in Uppsala, Sweden (reference number 2007/361).

## Mandibular Bone Graft Harvesting

Harvesting of cortico-cancellous chin grafts was performed under local anesthesia and sedation with either diazepam (10–25 mg, per oral Apozepam, Dumex-Alpha AB, Stockholm, Sweden) or midazolam (5–10 mg, Dormicum, Roche AB, Stockholm, Sweden). As a prophylactic measure, all patients received 2 g of V-penicillin (Kåvepenin, Astra AB, Södertälje, Sweden) and 500 mg of metronidazole (Fasigyn, Pfizer, Stockholm, Sweden) preoperatively and continued for 10 days. Anesthesia of the mandibular nerve and symphyseal region was induced by lidocain (2%) with epinephrine (1:80,000) (Xylocain/adrenalin, Astra AB). The mandibular symphysis was exposed through a mucosal and musculo-periosteal incision from canine to canine in the deepest part of the vestibule and the lip. A unicortical labial osteotomy was performed using a thin fissure bur. The osteotomies were prepared at least 5 mm inferior to the root tips and 4 mm superior to the mandibular inferior border. The bone graft was divided in the midline and harvested with a thin osteotome. The bone was kept in blood until particulated with a surgical bone mill (Tessiers Osseous Microtome, Mühlheim-Stetten, Germany). The periosteum, the muscle attachment, and the mucosa were carefully sutured in layers using resorbable sutures.

## Maxillary Sinus Augmentation Technique and Implant Placement

The sinus area was prepared under local anesthesia as described elsewhere.<sup>16,17</sup> In brief, after a crestal incision with a vertical releasing incision, a mucoperiosteal flap was elevated and reflected laterally to expose the lateral wall of the sinus. An approximately 20-mm-wide and 10-mm-high window was outlined with a round bur. The bone in the centre of the window was left attached to the Schneiderian membrane. Care was taken not to lacerate the sinus membrane during the elevation procedure. The Schneiderian membrane was accidentally perforated in 9 out of 30 sinuses. Autogenous bone particles were mixed with DPBB (Bio-Oss®, Geistlich Pharmaceutical, Wollhausen, Switzerland; particle size 0.25–1 mm) in an 80:20 mixture (mean 82:18) and fresh, autogenous blood from the wounds. Fibrin glue (0.5 mL) (Tisseel®, Duo Quick Immuno, Vienna, Austria) was added to increase the malleability of the graft material and to avoid the particles to migrate and accidentally penetrate perforations in the membrane. The

graft mixture was packed layer by layer and thrombin was added to catalyze the setting of the fibrin glue. Resorbable sutures were used to close the wound. Removable prostheses were not allowed the first 10 post-operative days and thereafter, the dentures were relined monthly with Viscogel® (Dentsply, York, PA, USA).

After a healing period of 6 months, 108 commercially pure titanium (c.p) implants with a turned (machined) surface (Mark II, Brånemark System®, Nobel Biocare AB, Gothenburg, Sweden) were installed in local anesthesia according to the manufacturer's protocol. Seventy-nine implants were inserted in grafted bone and 29 in residual bone. The implants were exposed after 6–8 months (mean 6.7 months) and healing abutments were connected. Two weeks later, healing abutments were changed to permanent abutments and all patients were rehabilitated with fixed bridges. Two oral and maxillofacial surgeons performed all surgical procedures.

### Clinical Follow-Up

All patients were asked for smoking habits and any clinical symptoms including nasal congestion, secretion, obstruction, or headache.

All bridges were removed (Figures 1 and 2), and the following variables were examined:

- Pocket depth at four sites of every implant (mesial, distal, buccal, and palatal)
- Bleeding on probing (BoP) at four sites (yes or no, measured on implant level)



**Figure 1** Occlusal view of the prosthetic situation in a patient 10 years after rehabilitation with bilateral sinus floor augmentation and subsequent implant placement.



**Figure 2** Same patient as in Figure 1, but after removal of the bridges prior to clinical evaluation of the individual implants.

- Mobility tested with forceps (mobile or not mobile)
- Resonance frequency analysis (RFA) by the means of the Osstell Mentor™ advice using a probe (SmartPeg Type II, Integration Diagnostics AB, Göteborg, Sweden) (Figure 3) manually inserted in the implant body after removal of the abutment. Data collected were expressed as Implant Stability Quotient (ISQ). An ISQ value between 1 and 100 is given where 1 is the lowest degree of stability and 100 the highest. The mean of four measurements per implant, two from the buccal side and two perpendicular to the first measurements, was used as the final ISQ value in accordance to the manufacturer's protocol.

All clinical examinations but RFA were performed before abutment removal. Afterward, all abutments and prosthetic constructions were reconnected and all screws tightened according to the manufacturer's



**Figure 3** Resonance frequency analysis (RFA) by the means of the Osstell Mentor advice using a probe.

protocol. Intra-oral radiographs were obtained for all abutments to secure proper connection. The screw holes were filled with silicon and light curing resin.

### Radiographic Examination

Before removal of the prosthetic constructions, intra oral radiographs were obtained for examination of the marginal bone level at the implants at baseline (abutment connection), 1, 3, 5, and 10 years of loading. All but the 10-year radiographic examinations were performed with a Philips Oralix 65 apparatus (Philips, Milano, Italy) using Kodak Ektaspeed Plus™ dental film (Eastman Kodak, Rochester, NY, USA). The intra-oral radiographs at 10-year follow-up were performed with Schick CDR wireless system, Schick Technologies, Inc. (Long Island City, NY, USA). Marginal bone measurements of the implants were made twice at the mesial and distal aspects from the reference point of the implants (0.8 mm apical to the implant/abutment connection) (Figure 4) by an experienced radiologist and a mean was calculated.

The radiographic examinations at 3 months, 1 year, and 2 years after grafting included panoramic radiographs and cross-sectional tomograms (Scanora technique for both). The measurements of the grafted area were estimated with a special ruler directly on the radiographs, taking the magnification into consideration (panoramic film  $\times 1.3$ , tomograms  $\times 1.7$ ). The maximal length, height, and width of the grafts were marked with a soft pen and measured to the nearest 0.5 mm. The height and width of the grafts were measured on the

Scanora tomograms and the height and length of the grafts were measured on the panoramic film. A mean of the height measurements were calculated.

Cone beam computed tomography (CB/CT) (i-CAT® Cone Beam 3-D Imaging System, Imaging Sciences International, Inc., Hatfield, PA, USA) was obtained at 10-year follow-up after removal of the prosthetic constructions including the abutments for detailed information of the grafted areas including the measurements of the graft. The maximal length, height, and width of the grafts were measured on the panoramic and axial view using the software in i-CAT® Vision. To test the repeatability of the measurements, the radiographs of 10 randomly selected patients were measured twice with a 6-month interval between measurements.

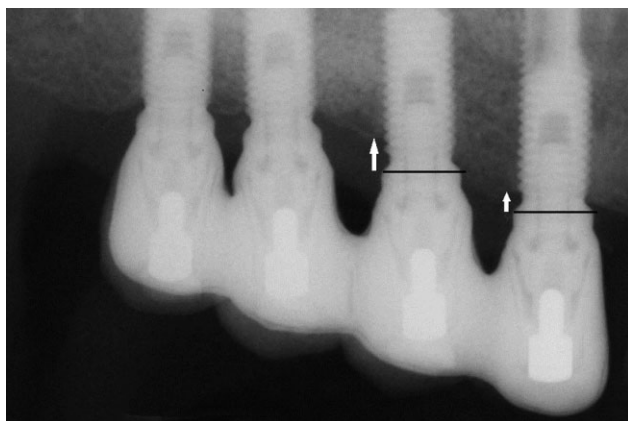
### Statistical Analysis

Results were reported as mean values and standard deviations. The experimental unit in the analysis was an individual implant, of which there were several within each patient. A model involving generalized estimating equations (GEE) was used for handling the repeated measures on patients in the analyses of effects of residual bone/graft, smoking habits on mean marginal bone level, mean pocket depth, and RFA at the 10-year follow up. The model was set up with residual bone/graft and smoking habits and their interaction as factors. The two first response variables were logged to improve the model fit. To analyze changes in marginal bone level with time, the model was set up with the main factors; residual bone/graft, smoking habits and time with the interaction term time  $\times$  smoking habits. All *p* values were adjusted for multiple comparisons using the Sidak correction method.

ANOVA for repeated measures was used to assess the differences with time in graft length, height and width. The chi-square test was used to analyze differences in BoP between implants placed in grafted bone and residual bone. A statistically significant difference was considered at  $p < .05$ . All statistical measurements were performed using SPSS version 17 (IBM®, SPSS Inc., Chicago, IL, USA).

### RESULTS

Clinical data of patients, installed and lost implants are presented in Table 1.



**Figure 4** Intra oral radiograph showing marginal bone measurements of the implants (white arrows) were made from the reference point of the implants (implant/abutment connection, black line).

Fourteen (5 smokers and 9 non-smokers) of the 20 patients included in the study were followed throughout the study period. These patients had 53 implants placed in 22 (6 unilateral and 8 bilateral) grafted maxillary sinuses and 15 implants placed in the adjacent host bone. Three patients were deceased, two were too ill to participate and one patient had moved; representing a total of 25 unaccounted for implants. Two patients (heavy smokers) lost 10 of totally 15 failed implants. Nine implants were lost before loading and 6 failures were recorded after loading. No implants were lost after 2 years. One implant was “sleeping” due to bad positioning (patient number 19, in residual bone) and was not included in the 10-year follow-up (Table 2). Two post-operative infections occurred after 3 weeks and they were both successfully treated with clindamycin (Dalacin®, Pharmacia, and Upjohn, Stockholm, Sweden), 300 mg  $\times$  3 for 10 days and local irrigation with saline. The 20 patients initially received 2 full and 26 partial fixed bridges. At 10-years follow-up, all but one of the examined patients had fixed prosthesis in

function based on the initially installed implants. One patient (heavy smoker) who lost all 6 implants had 6 new implants (with moderately rough surfaces) installed and the new fixed prosthesis is still in function after 10 years. No patients had any clinical symptoms from the grafted sinuses, i.e., no nasal congestion, no secretion or obstruction and no headache.

The cumulative survival rate (CSR), 86.1% after 10 years, was calculated based on 108 placed Brånemark implants and 15 implant failures in 6 patients and additional 25 implant dropouts (Table 2). Nine of the failed implants were placed in grafted bone and six were placed in adjacent host bone (Table 1).

The marginal bone levels, pocket depths, and ISQ values for all patients are presented in (Table 3).

The marginal bone levels, at 10 years follow-up, measured from the reference point (0.8 mm apical to the implant/abutment connection) of all implants were  $1.6 \pm 1.0$  mm (range; 0–5.9 mm), of implants placed in host bone were  $1.8 \pm 1.1$  mm (range; 0.6–3.3 mm) and of implants placed in grafted bone were  $1.5 \pm 0.9$  mm

**TABLE 1 Patient and Implant Data**

Patient	Gender	Smoker Baseline/ 10 Years	Implants in Residual Bone	Lost in Residual Bone	Implants in Grafted Bone	Lost in Grafted Bone	Total Failures	10-Year Follow-up
1	M	1	4	2	5	2	4	Deceased
2	F	0	1	0	3	1	1	Sickness
3	F	1	2	0	2	0	0	Deceased
4	F	1	0	0	2	1	1	Deceased
5	M	0/0	3	0	8	0	0	Yes
6	F	0/0	1	0	3	0	0	Yes
7	M	0	1	0	6	0	0	Moved
8	F	1/1	2	0	4	0	0	Yes
9	F	0/0	2	0	4	0	0	Yes
10	F	0	1	0	3	0	0	Sickness
11	F	0/0	2	0	4	0	0	Yes
12	M	1/1	1	0	3	0	0	Yes
13	F	0/0	0	0	4	2	2	Yes
14	F	0/0	0	0	3	0	0	Yes
15	F	0/0	1	0	6	0	0	Yes
16	F	1/0	0	0	4	0	0	Yes
17	M	1/1	0	0	3	0	0	Yes
18	F	0/0	1	0	6	1	1	Yes
19	F	1/1	3 (1 sleep)	0	4	0	0	Yes
20	M	1/1	4	4	2	2	6	Yes
Total failure rate		9/5	29 (26.9%)	6 (20.7%)	79 (73.1%)	9 (11.4%)	15 (13.9%)	

Non-smoker = 0, Smoker = 1.

**TABLE 2 Life Table**

Time	Implants Entering Interval	Failed Implants in Interval	Dropouts	CSR (%)
Placement to loading	108	9	0	91.7
Loading to 1 year	99	1	0	90.7
1–2 years	98	5	0	86.1
2–3 years	93	0	20	86.1
3–5 years	73	0	1	86.1
5–10 years	72	0	3 + 1 sleep	86.1
At 10 years	68			86.1

CSR = cumulative survival rate. [Correction made 12 March, 2013 after online publication: Loading to 1 year CSR (%) changed from 91.7 to 90.7 in Table 2]

**TABLE 3 The Number of Implants, Marginal Bone Levels, Pocket Depths and ISQ Values for All Patients and the Distribution in Host Bone and Grafted Bone**

Patient	Site	N	Marginal Bone Level Mean (Range) SD	Pocket Depth Mean (Range) SD	ISQ Mean (Range) SD
5	b	3	1.0 (0.6–1.7) $\pm$ 0.4	2.6 (2–3) $\pm$ 0.5	68.0 (58–75) $\pm$ 8.9
	g	8	2.1 (0.9–3.6) $\pm$ 0.7	2.7 (2–5) $\pm$ 0.8	68.4 (63–77) $\pm$ 4.5
6	b	1	1.1	2.5 (2–3) $\pm$ 0.6	74.0
	g	3	1.6 (1.1–2.2) $\pm$ 0.2	2.5 (2–3) $\pm$ 0.5	70.0 (66–75) $\pm$ 4.6
8	b	2	1.7 (1.4–2.4) $\pm$ 0.3	2.8 (2–4) $\pm$ 0.7	69.5 (64–75) $\pm$ 7.8
	g	4	0.8 (0–1.9) $\pm$ 0.4	3.3 (2–6) $\pm$ 1.2	68.2 (62–74) $\pm$ 5.1
9	b	2	2.2 (0.9–3.2) $\pm$ 1.2	4.4 (3–6) $\pm$ 1.2	67.5 (66–69) $\pm$ 2.1
	g	4	1.7 (1.1–3.1) $\pm$ 0.8	3.6 (2–7) $\pm$ 1.7	70.8 (59–79) $\pm$ 9.5
11	b	2	1.3 (1.3–1.4) $\pm$ 0.1	2.4 (2–3) $\pm$ 0.5	70.0 (70–70) $\pm$ 0
	g	4	0.7 (0.1–1.5) $\pm$ 0.5	2.6 (2–3) $\pm$ 0.5	67.2 (60–76) $\pm$ 7.1
12	b	1	0.8	3.5 (3–5) $\pm$ 1.0	79
	g	3	1.1 (0.4–2.4) $\pm$ 0.7	2.9 (2–5) $\pm$ 0.8	68.7 (62–81) $\pm$ 10.7
13	b	0			
	g	2	3.2 (0.2–5.9) $\pm$ 3.8	6.2 (3–9) $\pm$ 2.5	62.0 (58–68) $\pm$ 8.5
14	b	0			
	g	3	0.8 (0.8–1.1) $\pm$ 0.1	3.2 (2–5) $\pm$ 0.8	78.3 (75–84) $\pm$ 4.9
15	b	1	2.6	2.8 (2–4) $\pm$ 1.0	67
	g	6	2.4 (0–5.3) $\pm$ 2.0	3.1 (2–5) $\pm$ 1.0	61.7 (59–65) $\pm$ 2.2
16	b	0			
	g	4	1.0 (0.8–1.3) $\pm$ 0.1	2.7 (2–4) $\pm$ 0.6	73.8 (68–78) $\pm$ 4.2
17	b	0			
	g	3	1.4 (0.9–1.9) $\pm$ 0.4	2.9 (2–5) $\pm$ 1.0	78.0 (75–83) $\pm$ 4.4
18	b	1	1.4	2.8 (2–3) $\pm$ 0.5	71
	g	5	1.4 (1.2–2.0) $\pm$ 0.2	3.3 (2–5) $\pm$ 0.9	76.0 (55–89) $\pm$ 13.2
19	b	2	2.5 (1.5–3.3) $\pm$ 1.1	7.5 (6–9) $\pm$ 1.3	57.5 (57–58) $\pm$ 0.7
	g	4	1.8 (1.1–2.6) $\pm$ 0.4	5.7 (3–8) $\pm$ 1.3	73.0 (70–76) $\pm$ 2.6
20	b	0			
	g	0			
Total	b	15	1.8 (0.6–3.3) $\pm$ 1.1	3.6 (2–9) $\pm$ 1.9	68.3 (57–79) $\pm$ 6.7
	g	53	1.5 (0–5.9) $\pm$ 0.9	3.3 (2–9) $\pm$ 1.4	70.2 (55–89) $\pm$ 7.8
b + g		68	1.6 (0–5.9) $\pm$ 1.0	3.4 (2–9) $\pm$ 1.5	69.7 (55–89) $\pm$ 7.5

b = host bone, g = grafted bone, N = number of implants, ISQ = implant stability quotient, SD = standard deviation.

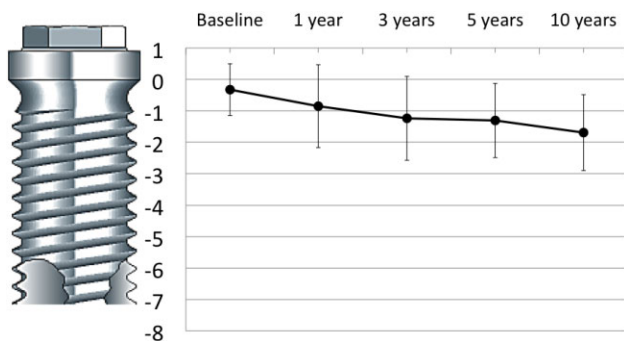
**TABLE 4** Marginal Bone Level at Abutment Connection (Base Line) and after 1, 3, 5 and 10 Years of Functional Loading

	Base Line (mm) Mean (Range) SD	1 Year (mm) Mean (Range) SD	3 Years (mm) Mean (Range) SD	5 Years (mm) Mean (Range) SD	10 Years (mm) Mean (Range) SD
Implants in grafted bone	0.4 (0–2) $\pm$ 0.9	0.7 (0–7) $\pm$ 1.5	1.1 (0–7) $\pm$ 1.5	1.2 (0–7) $\pm$ 1.4	1.5 (0–5.9) $\pm$ 0.9
Implants in host bone	0.2 (0–6) $\pm$ 0.5	0.8 (0–3) $\pm$ 1.0	1.3 (0–4) $\pm$ 0.9	1.4 (1–4) $\pm$ 0.9	1.8 (0.6–3.3) $\pm$ 1.1
All implants	0.3 (0–6) $\pm$ 0.8	0.8 (0–7) $\pm$ 1.3	1.2 (0–7) $\pm$ 1.4	1.3 (0–7) $\pm$ 1.3	1.6 (0–5.9) $\pm$ 1.0

SD = standard deviation.

(range; 0–5.9 mm). There were no statistically significant differences in marginal bone levels between implants placed in host bone or grafted bone ( $p = .16$ ) and not between smokers ( $1.4 \pm 0.7$  mm [range; 0–4.2 mm]) or non-smokers ( $1.6 \pm 1.1$  mm [range; 0.7–6.9]) [ $p = .89$ ] at 10 years follow-up.

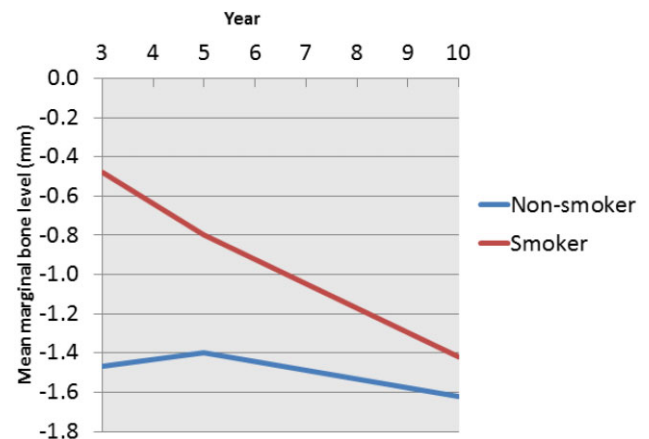
The mean pocket depths were  $3.4 \pm 1.5$  mm (range; 2–9 mm),  $3.6 \pm 1.9$  (range; 2–9 mm), and  $3.3 \pm 1.4$  mm (range; 2–9 mm), for all implants, implants placed in host bone, and implants placed in grafted bone, respectively. There were no statistically significant differences in pocket depths between implants placed in host bone or grafted bone ( $p = .59$ ), and there was no significant difference between smokers ( $4.1 \pm 1.9$  mm [range; 2–9 mm]) and non-smokers ( $3.1 \pm 1.2$  mm [range; 2–9]) at 10 years follow-up ( $p = .19$ ). The marginal bone levels of implants placed in host bone and grafted sites at base line (at abutment connection), 1 year, 3 years, 5 years, and 10 years are presented in Table 4 and Figure 5. The data on marginal bone level present for statistical analyses for each implant was available at 3, 5, and 10 years. Overall, a significant marginal bone loss occurred between the follow up at 3 and at 10 years ( $p < .001$ ).



**Figure 5** Marginal bone levels at the time of abutment connection (baseline) and after 1, 3, 5, and 10 years of functional loading.

This was mainly due to smokers who experienced a significant increase in marginal bone loss ( $p < .001$ ), whereas the bone loss among non-smokers was not significant ( $p = .871$ ) (Figure 6). There was no significant difference in marginal bone level from 3 to 10 years between implants placed in residual bone compared to implants placed in grafted bone ( $p = .811$ ).

None of the implants was found to be clinically mobile. The ISQ values (at implant level) for all implants were  $69.7 \pm 7.5$  (range; 55–89), for implants placed in host bone were  $68.3 \pm 6.7$  (range; 57–79) and implants placed in grafted bone were  $70.2 \pm 7.8$  (range; 55–89). There were no statistically significant differences in ISQ levels between implants placed in host bone compared with implants placed in grafted bone ( $p = .34$ ) and not between smokers ( $70.4 \pm 7.7$  mm [range; 57–83]) or non-smokers ( $69.5 \pm 7.6$  mm [range; 55–89]) ( $p = .95$ ) at 10 years follow-up.



**Figure 6** Changes in marginal bone levels (measured from the reference point) from 3 years to 10 years for smokers and non-smokers. The higher initial marginal bone level for the smokers must be read against the fact that 11 implants in three smokers had failed prior to 3 years in comparison to 4 implant failures in three non-smokers, i.e., we are looking at a skewed sample of smokers.

**TABLE 5 Results of the Radiographic Measurements of the Graft Length, Height and Width after Different Time Periods after Sinus Floor Augmentation**

	3 Months (mm) Mean (Range) SD	1 Year (mm) Mean (Range) SD	2 Years (mm) Mean (Range) SD	10 Years (mm) Mean (Range) SD
Length	19.8 (13.5–27.5) $\pm$ 4.3	20.0 (14.5–27) $\pm$ 3.7	19.4 (12–27) $\pm$ 4.0	19.1 (12–26.5) $\pm$ 4.0
Height	15.8 (11.5–21) $\pm$ 2.7	14.7 (10–20) $\pm$ 2.8	14.0 (10–19) $\pm$ 2.3*	13.3 (10–17) $\pm$ 2.1*
Width	12.4 (8.5–16.5) $\pm$ 2.7	12.0 (8–16) $\pm$ 2.9	11.5 (5.5–16.5) $\pm$ 3.2	12.0 (8–15) $\pm$ 2.1

\*Statistically significant difference  $p < .01$  when compared to 3 months (ANOVA).

SD = standard deviation.

## Radiographic Results

The measurements of the dimensional changes of the grafts in the 14 patients, at 3 months, 1 year, 2 years, and 10 years are presented in Table 5. There was a statistically significant reduction in height between 3 months and 2 years and 3 months and 10 years after grafting. However, there were no statistical significant reduction in height between 2 years and 10 years after grafting. There were no statistical significant differences in length and width in any of the time periods.

In 14 of the 22 grafted maxillary sinuses, there were no signs of any pathology in contact with the grafts, i.e., swelling of the Schneiderian membrane or fluid levels, observed in the CB/CT scans. In five of the grafted sinuses, a 1–6 mm swelling of the Schneiderian membranes was observed, and in three cases there were swellings of more than 6 mm (Figure 7). There was no significant difference between smokers and non-smokers.

## DISCUSSION

There is a need for longitudinal, prospective clinical studies to evaluate the long-term outcomes of implants placed after sinus floor augmentation.



**Figure 7** CBCT imaging (panoramic view) of a patient with bilateral sinus floor augmentation. Note the swelling of the Schneiderian membrane on the left side (white arrows) around the graft (black arrows).

In the present study, the overall survival rates after 10 years of implants with a turned surface placed in maxillary sinuses augmented with a mixture of DPBB and AB bone was 86.1%.

Several reviews have shown that implants with turned surfaces have lower survival rates than implants with moderately rough surfaces when used in combination with sinus floor augmentation.<sup>4,5,14,15,18–21</sup> The percentage of implant failure was usually higher in the first year. In a review of sinus floor elevation, Pjetursson et al.<sup>15</sup> found, in a meta-analysis, that the estimated annual implant failure rate was 3.48%, translating into a 3-year implant survival of 90.1%. However, in a separate analysis, the translating 3-year survival rate of implants with turned surfaces and moderately rough surfaces were 81.4% and 96.5%, respectively. Moreover, 8.1% of the turned surface implants were lost during healing phase compared to 1.1% of the implants with rough surfaces. This is in accordance with the present study where 8.3% of the implants were lost before loading (9 out of 108). Sixty % (9 out of 15) of the implant failures occurred before loading and the remaining (6 out of 15) failed within 2 years of loading, both in augmented and residual bone.

When clinical outcomes of turned and moderately rough implants, respectively, are compared, there seem to be very small if any differences in results under normal conditions and for mandibular implants.<sup>22</sup> Maxillary turned implants display significantly lower levels of success than moderately rough implants even in normal cases. In the mandible, if compromised situations such as smoking patients<sup>23</sup> or when using short implants,<sup>22</sup> the moderately rough surfaces outperform the older turned ones. The implants of the present study were in a compromised situation due to the grafting procedure, severe atrophy and immature bone, but most

implants despite their turned, minimally rough surface survived and functioned despite this, unless another compromised factor was added; that of smoking patients, resulting in clearly increased rates of failure. Smoking habits may explain the observation that there was a proportionally higher, although not significant, failure rate in residual bone.

Another factor that seems to have a negative effect on the implant survival rate is the absence of a membrane to cover the lateral window of the grafted area.<sup>14,15,24</sup> It has been suggested that membranes tend to increase bone formation and have a positive effect on implant survival,<sup>25</sup> however in another study there were no differences in implant survival rates without membranes or with resorbable or non-resorbable membranes.<sup>26</sup>

The use of implants with a moderately rough surface and a membrane for coverage of the lateral window might have increased the implant survival rates in the present study. However, 2/3 (10 out of 15) of the failed implants were lost in patients with heavy smoking habits, another known risk factor in sinus floor grafting and implant treatment. With respect to risk factors the inclusion criteria should have been restricted to non-smokers or at least less than 10 cigarettes/day.

All these risk factors seemed to be of greater importance in the initial healing process, since nine implants failed before loading and no implants failed after 2 years of loading.

The mean healing period of the graft in the present study was 6.7 months. It has been suggested that the mineralization process is incomplete 6 months after the sinus augmentation procedure and new bone formation increases up to 12 months.<sup>27</sup> Ferreira et al.<sup>24</sup> presented survival rates of implants with turned surfaces of 97% after sinus floor augmentation with 100% DPBB. They suggested that a longer healing period (10 to 12 months) may improve graft maturation and graft quality and subsequently improve survival rates of implants with turned surfaces. In a recent study, maxillary sinuses were augmented with DPBB and AB harvested from the lateral sinus wall. After a healing period of 9 months implants with moderately rough surfaces were installed giving a survival rate of 98.9% after 9–34 months, mean  $27.5 \pm 23.8$  months.<sup>3</sup> The survival rates in the present study may have increased with a prolonged healing time and subsequent maturation of the graft. In addition, an alteration of the drilling protocol

could have been performed in order to enhance primary stability of the implants. Unfavorable forces from the mandibular dentition could also contribute to the early failure rates.<sup>28</sup>

Tisseel® was used as an adjunct to the mixture of DPBB and AB to make the graft material easier to handle and to hinder the particles to migrate which is particularly important in case of perforation of the Schneiderian membrane. However, it has been suggested that Tisseel® may jeopardize the integration of BioOss® particles with bone tissue, at least when used for lateral augmentation in a dog model.<sup>29</sup> On the other hand, in an experimental study on critical calvarial defects in rats, it has been concluded that Tisseel® may be an alternative therapy for regenerating bone in defects used in combination with particulated dentin.<sup>30</sup>

Marginal bone resorption in this clinical situation indicated an average bone loss of about 0.8 mm at 1 year, about 1.2 mm at 3 years and about 1.6 mm at 10 years. The figures indicate that a grafting situation such as the one investigated in this paper takes longer time for reaching steady state bone levels than implants placed in pristine bone that commonly lose bone in the first year, but not so much afterwards. However, an accumulated marginal bone loss of 0.4 mm between 3 and 10 years of follow up indicate that a steady state situation has at last been developed. Despite a somewhat higher and more prolonged initial bone loss in these grafted cases, the situation stabilized with time. These observations support Sundén Pikner,<sup>31</sup> that implants with a somewhat high marginal bone loss commonly lose a major part of this bone in the first 2 years but thereafter further bone loss levels off. Discussing only average marginal bone loss and finding this to have leveled off does not contradict the possibility of individual mishaps of course, but in general it seems like the bone situation has stabilized and that further problems with the anchorage of these grafts appear unlikely.

The unexpected, somewhat less marginal bone loss among smokers compared to non-smokers found after 3 years might be explained by the fact that 11 implants in three smokers had failed prior to 3 years, in comparison to 4 implant failures in three non-smokers, i.e., we are looking at a skewed sample of smokers. However, from 3 to 10 years, smokers lost more bone than non-smokers, which is what should be expected.

There were no changes in length and width from 3 months to 10 years after sinus floor grafting, but there

was a significant decrease in height of approximately 10–15% between 3 months and 2 years and 3 months and 10 years. There was no significant decrease in height between 2 years and 10 years. These results are in accordance with other studies evaluating the vertical changes of different graft materials for sinus floor augmentation<sup>32–34</sup> and DPBB seemed to have less height and volume reduction than AB.<sup>35,36</sup>

In the present study, the changes in marginal bone levels, length, height, and width of the graft were performed with different radiological equipment and techniques. There is a problem with long-term studies and the development of new techniques because some of the equipment no longer is in use. To the best of our knowledge, there are no studies comparing measurements of marginal bone level between conventional and digital radiographs regarding dental implants, however, in a clinical study comparing these two methods in detecting alveolar bone loss around teeth, no statistical significant differences were found for the periapical radiographs averaged for the whole mouth and for the bite-wings in the maxillary posterior regions.<sup>37</sup> Horizontal measurements in the panoramic film are less reliable due to variations in the magnification, however, if the patient is correctly positioned in the unit and when the form of the object is rounded, the distortion is less marked.<sup>38</sup> Hence, the absence of dimensional changes in length should be interpreted with care.

After longer healing periods following sinus floor augmentation, it could be difficult to distinguish between the grafted bone and the residual bone. However, DPBB seemed to increase radiopacity of the graft and subsequently facilitate identification of the inferior border of the graft even though it was difficult in some cases.

## CONCLUSIONS

Within the limits of the present study, the investigation demonstrated that the first 2 years after placement of implants with turned surfaces placed in sites after sinus floor augmentation with DPBB and AB seem to be critical for implant survival. Even though there was a small reduction of the graft height after 2 years, there was no progression of the graft reduction up to 10 years after sinus floor augmentation. At 10 years follow-up, the remaining implants presented excellent clinical and radiological results regardless of smoking habits or implant sites (augmented or residual bone), however

there is a need of prospective studies with larger populations to confirm these results.

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