Maxilla Sinus Grafting With Marine Algae Derived Bone Forming Material: A Clinical Report of Long-Term Results

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Purpose: Autogenous bone grafting continues to be considered the gold standard for sinus grafting. For the past 15 years the author has used an alternative graft material and followed-up the input/output statistic of implants to evaluate if this material results similar to the autogenous bone graft. Histomorphometric evaluations of graft materials show how much new bone is formed and if the graft material is resorbed.

Materials and Methods: In our study we used a marine derived carbonated red algae that is chemically converted into hydroxyapatite (HA). This material is distributed worldwide as the Communauté Européenne approved material AlgiPore (Dentsply Friadent, Mannheim, Germany), as the US Food and Drug Administration approved material C GRAFT (The Clinician Preference LLC, Golden, CO), and the Russian approved material AlgOss (Unexim Co, Moscow, Russia). A total of 209 sinus grafts were performed on 118 patients who presented with a severely resorbed maxillary alveolar process with 1 to 5 mm (mean, 3.6 mm) of remaining bone. The available bone was comparable to Class D bone as described by Simion et al. After 6 months implants were placed and 6 months later the implants were loaded.

Results: From September 5, 1990, to September 1, 2004, the author performed 209 sinus grafts on 118 patients. The longest observation period of loaded implants in this study is 156 months (13 years). Implant loss was 27 out of 614 loaded implants (4.4%), showing a survival rate of 95.6%. Smokers and women over 50 are included. Although AlgiPore/C GRAFT/AlgOss (ACA) undergoes a resorption process, we found only 14% volume loss after 6.4 months compared with 49.5% after 6 months when autogenous bone was used.

Conclusion: This retrospective study of over 14 years shows once again that the sinus lift procedure with grafting of the sinus floor and subsequent implant placement is a proven method. This 14-year longitudinal study shows that the marine derived HA material ACA in a mixture with approximately 10% autogenous collector bone and blood or platelet rich plasma is able to enhance enough new bone in 6 months to allow implant osseointegration after 6 more months with a high implant survival rate.

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In the resorbed partial or completely edentulous maxilla the amount of bone available for implant placement is often insufficient. In patients who have a normal maxilla-mandible relationship of the jaws according to height and depth, onlay grafts may be unfavorable in attempting to provide an esthetic, functional, and satisfying prosthetic rehabilitation. This has led some authors to propose that this area should be grafted using autogenous bone grafts (eg, the “gold standard,” from the iliac crest) to facilitate implant placement. This technique of iliac crest grafting has been reported by many authors.

Autogenous bone is the material of choice, but its use is limited by donor-site morbidity, complications, sparse availability, uncontrolled resorption, and marked volume loss.

Other graft sites for autogenous bone had been reported, such as the cranial vault and intraoral sites from the chin. Uncontrolled resorption of the graft material results in loss of volume in the gained augmentation height after sinus graft procedure. Many authors have reported resorption...
with a volume loss of up to 49.5% 6 months after sinus grafting.

In addition, patients tend not to accept autogenous bone grafting because it involves 2 surgical locations and general anesthesia is usually necessary for extraoral harvesting. These objections have led many surgeons to use other materials including allografts, tricalciumphosphate, hydroxyapatite, glass ceramic, and composite grafts composed of mixtures of allografts, xenografts, and alloplastic materials.

To enable functional loading of the implants, the graft material should resorb and be replaced by newly formed bone which then undergoes physiologic remodeling.

**Sinus Lift Procedure**

The maxillary sinus makes a good graft recipient for augmentation material because of the good surrounding bone and the fact that no mechanical stress is placed on the graft site. According to Lexer, this situation means a very good transplant bed for the sinus augmentation material.

**Implant Survival Rates**

Many authors have reported that the posterior maxillary bone is responsible for a very high rate of implant losses. However, the recent literature concerning sinus grafts showed very different long term results depending on which bone graft material was used.

Using autogenous bone, there have been survival rates reported between 54.5% and 78.75% with different long recall times. Using autogenous bone together with xenograft mixture there are survival rate reports of 85.7% up to 93.5% with different long recall times.

Survival rates using Bio-Oss (Geistlich, Schlieren, Switzerland) and demineralized freeze-dried bone allograft have been reported to be up to 94.5% after 6.5 years of recall.

This article compares the reported rates with the author’s own results found in his sinus grafted patients using AlgiPore (Dentsply Friadent, Mannheim, Germany), C GRAFT (The Clinician Preference LLC, Golden, CO), and AlgOss (Unexim Co, Moscow, Russia) (ACA).

**Sinus Lift Operating Method**

From September 5, 1990, to September 1, 2004, the author performed 209 sinus grafts on 118 patients with severely resorbed maxillary sinuses with 1 to 5 mm (mean, 3.6 mm) of remaining bone.

All 209 sinus grafts were augmented with a mixture of about 90% ACA and 10% autogenous collector bone gained from the bone trap and mixed either with venous blood or platelet rich plasma (PRP). In a second stage operation, after 6 months of primary healing, 614 implants were placed in 209 sinus grafted sites on these 118 patients (Fig 1). Six months later the implants were again loaded by means of different prosthetic appliances (Fig 2).

The patients underwent a very precise follow-up with a 6-month recall interval. The postoperative as well as the later complications were recorded and an input/output implant loss statistic was produced.
All patients received both clinical and radiographic examinations. Panoramic x-rays, lateral cephalograms, and dental computed tomographies were taken. All patients were treated under general anesthesia.

In this described group all patients presented with a severely resorbed maxillary alveolar process with 1 to 5 mm (mean, 3.6 mm) of remaining bone.

The available bone was a little less than Class C according to the site classification proposed by Jensen, comparable with Class D presented by Simion et al. Implants were placed after 6 months and 6 months later the implants were loaded.

The operative approach is via an entrance to the piriiform recess as described by Boyne and James, Tatum, and Loukota et al.

According to the anatomic investigation of Solar et al, we attempt to preserve the superior posterior alveolar artery by preparing a trough, starting posterior to the canine apex and continuing back to the area of the tuberosity.

To achieve this we prepare a trough with the drill or the Piezo surgery instrument according to Vercellotti and Lambrecht et al.

Elevating the sinus mucosa was performed using either the sinus lift instruments designed by Dr Kirsch from the Dentsply Friadent Company or the Piezo surgery unit from the Mectron Medical Technology Company (Carasco, Italy).

We believe that we do not need the elevated bone beneath the sinus mucosa as a protecting shield. Rather, we collect the drilled bone in the bone trap and use this autogenous material as part of our graft material.

The most common complication during this procedure is a perforation of the sinus mucosa around the septae, which Zuckerkandl first described.

We always suture the perforated mucosa membrane with a 7/0 resorbable suture material and apply a small piece of collagen membrane (Reguarde, The Clinician’s Preference LLC) or a nonresorbable PTFE membrane cytoplast (Osteogenics Biomedical, Inc, Lubbock, TX) and fix these membranes with titanium tacks to stabilize the membranes and prevent the augmentation material from dislocation.

The titanium and cytoplast membranes are removed before placing the implants 6 months later. Figure 5A shows the situation before filling and Figure 5B shows the situation after filling with graft material and before applying a titanium membrane. Figure 5C shows the situation after reopening 6 months later, before removing the membrane. Figure 5D shows the site after removal of the membrane.

### Sinus Floor Graft Material

In our study we exclusively used an augmentation material that is a nonanimal, biological material derived from the calcium-encrusted marine algae *Corallina officinalis* called AlgiPore/C GRAFT/AlgOss (ACA). The manufacturing process involves thermal treatment of the native algae and hydrothermal transformation of the calcium carbonate (CaCO₃) into hydroxyapatite (Ca₅(PO₄)₃(OH)). The organic components are completely removed during the production process. The final product consists of a minimum 98% apatite phase and the material has an interconnecting microporous structure. This material is distributed worldwide as the Communauté Européenne approved material Algi-Pore, the US Food and Drug Administration approved material C GRAFT, and the Russian approved material AlgOss.

The unique 3-dimensional, morphologic structure of the calcite skeleton of the raw algae is maintained from the beginning through the production of the final material. Details of the apatite ultrastructure can be seen in a scanning electron micrograph (Fig 3A). The particles of the biomaterial contain a regular arranged pore system (mean diameter of pores, 10 μm). They are periodically septated (mean length of interval 50 to 100 μm) and interconnected through microperforations (mean diameter of perforations, 1 to 3 μm) (Fig 3B, C). The specific pore volume of the bioceramic averages 1.07 cm³/g, while the specific area averages 32 to 50 m²/g.

Our augmentation material consists of about 4 mL ACA mixed with approximately 0.4 mL collector bone out of the bone trap and with about 1.5 mL venous blood or PRP (Fig 4). If we are using PRP, we are adding 0.5 mL thrombin (Baxter). This mixture is very moldable and has a cake-like consistency; it is easy to apply into the sinus recess through the trough.

After filling the sinus recess and placing the material with enough force to fill the complete cavity we apply a titanium membrane (Frios Bone Shield, Dentsply Friadent) or a resorbable collagen membrane Reguarde (The Clinician’s Preference LLC) or a nonresorbable PTFE membrane cytoplast (Osteogenics Biomedical, Inc, Lubbock, TX) and fix these membranes with titanium tacks to stabilize the membranes and prevent the augmentation material from dislocation.

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### Human Histology Results After Sinus Graft

Before implant placement in the grafted sinus we harvested 797 core samples taken after different healing times and prepared these core samples to histology sections according to the method of Donath. From these histologies we are able to demonstrate the immense resorption kinetics of ACA.
Figure 6 shows the ACA granulate partially resorbed and the lower pores are filled with newly formed bone. In Figure 7, most of the tubuli are filled with cells or they are creeping into it. The biomaterial ACA gets resorbed either enzymatically or by osteoclasts. In Figure 8, the osteoclasts have formed a huge lacuna (yellow circle). The black arrow shows the collagen fibers preceding the borderline of the calciogenesis (black line). Figure 9 shows the extremely good osseointegration of the ACA particles. We achieved this excellent result with an addition of PRP to the augmentation mixture.

Figure 10 shows, because of the long healing time, the almost complete formation of trabecular bone structures with the remodeling processes. Most of the ACA particles are surrounded by newly formed bone in different maturation phases. This emphasizes the good osseointegration caused by the excellent resorption kinetic and the new bone formation.
FIGURE 5. A, After drilling the trough and elevating the unperforated mucosa (asterisks). B, The piriform recess is completely filled with graft mixture (ACA) mixed with 10% autogenous collector bone and venous blood or PRP before covering with a membrane. C, Reopening 6 months later before removing the titanium membrane (Frios Bone Shield, Dentsply Friadent). D, The grafted site is completely closed with newly formed bone.


FIGURE 6. This is a 20× histology enlargement of a specimen taken from a 73-year-old woman after 11 months’ healing time. The ACA granule is partially resorbed and the lower pores are filled with newly formed bone. The 2 asterisks show 2 osteons and the bone is filled with many vital osteocytes. The lower portion of the granules is resorbing (black arrows) and the pores are filled with osteoid material (yellow arrows).


FIGURE 7. This is a 40× magnification of a histologic section with cellular migration in the specimen of a 65-year-old woman after 11 months’ healing time. Most of the tubuli are filled with cells, or the cells are creeping into the tubuli. The biomaterial ACA resorbs either enzymatically or by osteoclasts.

formation, what we call creeping substitution (replacement resorption). Because of the netlike connection between the particles, the newly formed bone becomes a trabecular structure comparable to the normal human spongy bone structure.

**Histomorphometric Results**

Out of these 797 core specimens, Schopper et al.66 investigated 68 sections from 26 patients with 136 measurement frames in a mixed model analysis. The histomorphometric analysis showed 23% new bone, 33% bio-ceramic, and 44% marrow space (Fig 11). The calculation of bone showed no significant differences between premolar and molar region for sex, age, sampling interval, and sampling site.

**Results Using PRP in the Graft Material**

Since 2000 we have been using PRP according to Marx et al.67 in connection with ACA and approximately 10% collector bone out of the bone trap. In a group of 29 sinus lifts we found after a mean healing time of 7.5 months 28.95% new bone formation versus 23% of new bone without PRP. In addition, there was only 21.75% of nonresorbed ACA material when
using PRP as opposed to 33% without PRP. This is an increase of 26% of new bone and a decrease of 33% of biomaterial compared with Schopper et al.

We do not yet know if there is a correlation between acceleration of ceramic resorption by PRP and consecutive acceleration of new bone formation or vice versa. This phenomenon is not seen with non-resorbable materials.

Clinical Results

The longest observation period of loaded implants in this study on 614 implants placed in 209 sinus grafted sites on 118 patients is 156 months (13 years). We used IMZ, Frialit 2, and Xive implants (Dentsply Friadent). The implant survival rate was calculated as an input/output analysis.

Implant loss was 27 out of 614 loaded implants (4.4%), showing a survival rate of 95.6%. Smokers and women over 50 are included. Unlike Mayfield et al and De Bruyn and Collaert, we did not find a statistically significant increase of implant losses in smokers.

Although ACA undergoes a resorption process, Wanschitz et al found only 14% volume loss after 6.4 months compared with 49.5% after 6 months when autogenous bone was used. Schlegel et al and Hatano et al also reported this immense volume loss.

Complications

The major complications during the operation were perforating the mucous membrane. Chanavaz reports about 7%, Raghoebart et al about 17%, and Sullivan et al about 30% intraoperative perforations of the mucofa. We had a perforation rate of 20.6%. These perforations were always sutured and usually covered with a collagen membrane like Reguard (The Clinician’s Preference LLC). Additionally, in larger defects we sealed the suture and the collagen membrane with fibrin glue (Baxter) according to Sullivan et al.

The sinus osteotomy was covered with the titanium membrane Frios Bone Shield (Dentsply Friadent). Dehiscence over these membranes was the most common complication. We preferred to use these membranes as we always found the best guided bone regeneration beneath this material. We had 28% mucosal dehiscences over the titanium membranes, which were more often than reported by Simion et al. In spite of this frequent exfoliation, we had 98% primary bone consolidation beneath this material, similar to Otto et al, who reported more bone consolidation than when resorbable membranes were used. Local irrigation and cleansing were necessary to treat the membrane dehiscence; 18% of the titanium membranes had to be removed before implant placement but never earlier than 8 to 10 weeks after the sinus graft surgery.

Local infections occurred in 12% of our cases. Either the mucosa had to be sutured a second time or local irrigation and cleansing was necessary. A major infection occurred in only 1 case. This led to a submucous abscess with an acute maxillary sinusitis, which healed without incident after incision, drainage, and antibiotics; 3 implants were placed 6 months later. One implant was lost after 1 month, and a second was lost after 42 months. A second sinus graft using ACA was performed and the lost implants were replaced.

We did not see a high percentage of sinusitis as reported by Kahnberg et al. Postoperative maxillary sinusitis was not an issue in our patient group. This may be because of the suturing and covering of perforations with a collagen membrane and sometimes sealing it with fibrin glue.

Discussion

Since the initiation by Tatum, the publication by Boyne and James, and later by Tatum, the so-called “sinus lift” has become a common method of operation to treat the atrophied posterior maxilla to place dental implants. Many reports have discussed the anatomy of the maxillary sinus configuration, the bone structures, quality of bone, and the blood supply. To evaluate the different operating procedures there are reports of qualifying the different atrophy grades.

Because the position of the maxillary sinus is difficult to evaluate in a 2-dimensional x-ray, we along with Hatano et al recommend using the computed tomography on a “dental CT” preoperatively to identify the size of the maxillary sinus and bone and to evaluate postoperative measurements of the achieved height and volume.

Following the studies by Solar et al, the surgical approach to the sinus membrane was modified by preparing a trough (Fig 2) to avoid damage to the superior posterior alveolar artery. This enables a better blood supply for the augmented material. Preserving the lifted bone of the window, as described by Tatum, Loukota et al, and Raghoebart et al, is not as good as collecting this autogenous bone in the bone trap and incorporating it into the augmentation material. By doing this, there are living cells in between the ACA material.

Operative procedures as described by all the initiating authors always emphasize the importance of preserving the integrity of the sinus mucosa. As previously noted, we always try to obtain a primary
closure by suturing the perforated mucosa and covering it with a collagen membrane. In larger defects the collagen membrane is sealed with fibrin glue (Baxter) according to the suggestion of Sullivan et al.54

Various graft materials are available, but autogenous bone is still considered to be the gold standard.4,6,46 Many authors have reported the use of inorganic bovine bone.27,77,78 But these materials, such as Bio-Oss, undergoes slow resorption36,79-82 or in some instances no resorption for up to 7 years (as confirmed by clinical biopsies and histology [Fig 12]).83-86

Nonresorbable graft materials like glass ceramic28,30,87 or highly sintered bovine material will not remodel, will not show any immunologic response and will not adapt functionally to the remodeling surrounding bone.35 Because these materials do not resorb at all, Merten et al.86 call them “foreign body materials.” These materials do not remodel and do not adapt functionally to the bone of the transplanted bed.84,86 For bone morphogenesis, the structural architecture and chemical properties are crucial.62,88 Animal studies97 and human histomorphometric studies66,89,91 have shown that the marine algae derived HA material ACA is interconnecting porous, osteoconductive, shows a high absorption rate, and resorbs.89

Only a resorbable material will adapt to the surrounding bone,14,16,35 and once the augmentation material has been replaced there is no foreign material left and the normal remodeling process is able to begin. Figure 13 shows the histology of a core sample taken by Dr Haessler 6 years after an ACA sinus graft. At low magnification some remnants of this algae derived resorbable material are visible. The whole area is filled with mature spongy bone.

Only newly formed bone without “foreign bone material” is able to withstand the physiologic functional load.

A certain amount of resorption begins shortly after ACA is inserted. This material shows a favorable resorption kinetic as there is minimal volume loss after 6.5 months,71 which is compared with autogenous bone.17,19 According to Ulm et al,74 the new bone values are very similar to the percentages of new bone formation we found (average 23%). As was found in other investigations, there is an increase of new bone formation and decrease of ACA material the longer the healing time (D. Moser, personal communication, 2004).29 The results of this study with synthetic material are comparable with studies using autogenous bone,6,92,93 and studies on other augmentation materials such as Cerasorb (Curasan, Kleinostheim, Germany)26,94,95 or Bio-Oss96-101 regarding new bone formation.

Our excellent survival rate of 95.6% is probably due to the material features: porosity, absorption, and resorption, and is excellent compared with autoge-
of autogenous bone.18,19 This acceleration of new bone formation can again be explained by the features of porosity, absorption, and resorption.

Similar results have been reported by Fennis et al,102 Oyama et al,103 and Schlegel et al104 using autogenous bone using Cerasorb105 and using ACA.29 Some authors have reported poor results using PRP.106,107

The results have not been positive, especially in those studies where the augmentation material was the highly sintered nanoporous bovine material Bio-Oss.108-111 It is not surprising that these studies with inorganic bovine bone like Bio-Oss do not see an acceleration of new bone using PRP because this highly sintered foreign body material86 is not porous enough to bind to the PRP62 or autogenous osteoblast cultures,112-114 as well as to bone morphogenetic protein,115 and is not rebuilding as much new bone as other materials such as ACA.115

**Conclusion**

This retrospective study of over 14 years shows once again that the sinus lift procedure with grafting of the sinus floor and subsequent implant placement is a proven method.

The good implant survival rate of 95.6% with a follow-up time of up to 13 years in this study proves that the sinus floor grafting after sinus lift is an adequate method to solve the problems of the atrophied posterior part of the maxilla allowing dental implants with a fixed prosthetic.

Additionally, this 14-year longitudinal study shows that the marine derived HA material ACA in a mixture with approximately 10% of autogenous collector bone and blood or PRP is able to enhance enough new bone in 6 months to allow implant osseointegration after 6 more months.

This and other reports show very clearly that autogenous bone with all its pitfalls in harvesting, donor site morbidity (such as pain,7,9 nerve disturbances,8 complications,10,12 sparse availability,13 uncontrolled resorption,15,16 and marked loss of volume17-19) may not be the superior graft material for sinus floor augmentation. An allograft like the marine derived HA material ACA shows comparable and in some cases better results.

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