
Augmentation of the Maxillary Sinus with Calcium Sulfate: One-Year Clinical Report from a Prospective Longitudinal Study

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The aim of the present investigation was to evaluate the clinical and histologic results of a sinus augmentation procedure performed using calcium sulfate as the grafting material. A group of 12 patients (15 sinuses) formed the pilot group. Based on the experience of the pilot group, the technique of calcium sulfate application was modified, and a second group of 45 patients (50 sinuses) was subsequently treated (test group). In the pilot group, a total of 30 implants (Bioblock) was placed. In the test group, a total of 100 implants (Bioblock and Biohorizons) was placed. The clinical data reported in the present study are related to the 1-year follow-up for both groups.

Clinical evaluations, including assessment of implant mobility and probing pocket depth, were recorded on a monthly basis following implant uncovering until final prosthesis placement, and every 6 months thereafter. Radiographs were taken prior to sinus augmentation, monthly until 6 months postoperatively, 9 and 12 months after implantation, and at yearly intervals thereafter. One implant in the pilot group was not integrated at second-stage surgery, and 1 in the test group failed to maintain osseointegration after the abutment connection (at the 1-year evaluation). Based on defined criteria, the overall success rate for the 130 placed implants 1 year postimplantation was 98.5%. Clinical and radiographic evaluation revealed that the augmentation procedure resulted in new tissue formation within the sinuses. The technique used in the test group suggested a slowdown in material resorption and a reduction in graft shrinkage during healing. Bone biopsies were harvested for histologic evaluation. The application of a resorbable barrier membrane to the access window reduced the invagination of soft tissue at that level. The results of this study support the hypothesis that calcium sulfate may be a suitable material for sinus augmentation.

(INT J ORAL MAXILLOFAC IMPLANTS 1999;14:869-878)

Key words: calcium sulfate, dental implant, histology, implantology, maxillary sinus augmentation, oral surgery

Rehabilitation of patients with edentulous posterior maxillae represents a challenge when an implant-supported restoration is the treatment of choice, because of alveolar bone loss and maxillary

sinus pneumatization. Different surgical techniques have been proposed to address this clinical problem: maxillary sinus floor augmentation,¹ Le Fort I osteotomy with interpositional bone graft,² segmental bone onlays,³ and subperiosteal implants. In situations where the interarch distance is normal or reduced, augmentation of the maxillary sinus through a grafting procedure is probably the preferred approach. This procedure is meant to produce the formation of new bone in the lower portion of the maxillary sinus, thus increasing the height of crestal bone available for implant placement.⁴⁻⁶ Infraction of the lateral wall of the maxillary sinus provides access for sinus membrane elevation and graft placement. However, yet to be definitely determined are the best graft material,

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whether immediate or delayed implant placement is desirable, the best implant surface (hydroxyapatite-[HA] coated versus titanium, rough versus smooth)⁷ and design (cylindric versus threaded cylinder).

A wide variety of grafting materials have been used to augment bone volume within the sinus: autogenous bone from the iliac crest and oral cavity,⁸⁻¹⁴ as well as bone substitutes, such as demineralized freeze-dried bone allografts (DFDBA),^{1,11,15} resorbable^{1,16} and nonresorbable HA,^{1,12,15} and xenografts.^{1,11,15,16}

Autogenous bone has always been considered the gold standard for grafting,^{4,9,14,17} but it also has disadvantages, including: (1) limited amount of available graft material,¹⁷ (2) an additional surgical site, (3) donor site morbidity, and (4) the requirement of general anesthesia for extraoral bone harvesting.^{17,18} Demineralized freeze-dried bone allograft has been used for sinus augmentation by several authors, who reported good clinical results.^{10,17,19-21} On the contrary, recent findings suggest that the DFDBA particles within the sinus may undergo a slow and unclear remodeling process, leading to compromised bone quality and insufficient quantity for implant placement.²² Some authors have noted that nonresorbable HA and bovine bone could be unsatisfactory for bone augmentation because the first does not integrate with implants,^{16,23} while the latter may yield inconsistent results with minimal new bone.²⁴ Thus, even though clinical reports and experimental research have attempted to evaluate, and sometimes even to compare, different grafting materials, the debate still continues as to the best graft materials for sinus augmentation.^{8,16,17,21,22}

Plaster of Paris (calcium sulfate) was one of the first bone substitutes to be used by Dreesman in 1892.²⁵ Subsequent studies showed normal²⁵⁻²⁷ or accelerated^{25,28} bone regeneration when calcium sulfate was used to treat bony defects. Pecora et al reported the use of medical-grade calcium sulfate hemihydrate (MGCSH) as a grafting material for sinus augmentation and concluded that it was a promising graft material, yielding the production of adequate quantity and quality of new bone for implant placement.²⁹ Histologic examination of the specimens harvested from the treated patients showed complete calcium sulfate resorption, thus confirming the findings of other authors.²⁶ The major concern emanating from that experience was related to the fast resorption trend of the material and the reduction in mass seen during healing. The purpose of the present study was to evaluate the clinical and histologic results of maxillary sinus augmentation procedures, for the placement of

endosseous dental implants, performed using calcium sulfate as grafting material in a large group of patients. Two different types of implants (HA and titanium plasma-spray) were used. The present article reports the 1-year follow-up data.

Materials and Methods

The present study comprised 2 patient groups; the first (pilot group) consisted of patients who volunteered for a clinical trial, while the second (test group) was treated at a later stage with a slightly modified surgical technique, based on the results and the experience of the first group. The following selection criteria were adopted for patient inclusion in the study:

1. Absence of significant risk factors (chronic steroid therapy, significant cardiovascular disease, radiation to the maxilla, heavy tobacco smoking, uncontrolled diabetes, chemotherapy)
2. Absence of sinus cysts or ongoing sinusitis
3. Presence of mono or bilateral maxillary edentulism involving at least the first, second, and third molars of each quadrant, with a residual alveolar ridge height (distance between the crest of the alveolar ridge and the floor of the maxillary sinus) of between 1 and 7 mm.

Each patient was to receive 1 implant per missing tooth. The implants considered in the present study were all placed within grafted bone, either simultaneously or with a staged approach. The implants used were either 3.75 × 15 mm (Bioblock, Deerfield Beach, FL) or 4 × 13 mm (Biohorizons Implant Systems, Birmingham, AL). Thus the implants protruded into the grafting material (or the newly formed bone, if the implant was placed at a later stage) 6 to 14 mm, depending on the type of implant and the height of residual bone. The opposing dentition consisted of natural teeth in 45 patients, prostheses or single crowns supported by natural teeth in 6 patients, and implants in 9 patients.

Pilot Group. Twelve healthy patients (7 females and 5 males) requiring maxillary sinus augmentation for implant placement were selected. The mean age was 48.1 (range 30 to 71). Heavy smokers (more than 5 cigarettes/day) were excluded from the study. A thorough presurgical evaluation, including the study of mounted diagnostic casts and a diagnostic wax-up, was carried out. The radiographic examination included both conventional panoramic radiography and computed tomography. Altogether, 15 sinuses were treated.



Fig 1 Access window prepared through the maxillary sinus lateral wall (pilot group patient).

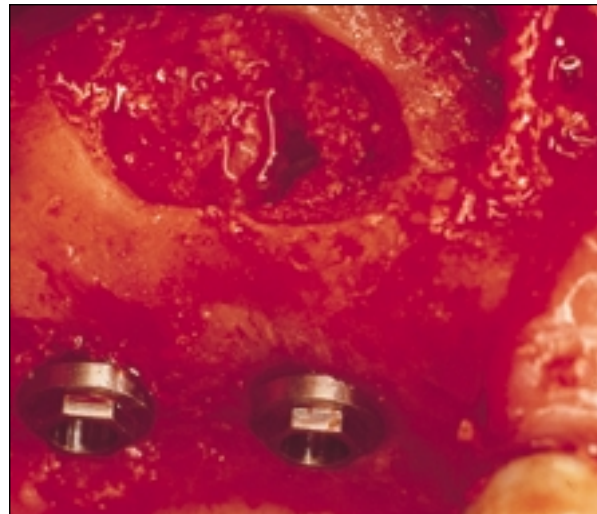


Fig 2 Implants are placed in the sinus, which is partially filled with calcium sulfate.

Table 1 Implant Clinical Results			
	Pilot group	Test group	Total
Placement data			
Immediate implants	16	40	56
Staged implants	14	60	74
Implant type			
TPS screws	30	75	105
HA-coated	0	25	25
Success/failure data at 12 months			
Successful implants	29	99	128
Failed implants	1	1	2
Total implants	30	100	130

Preoperative medication consisted of antibiotic coverage with amoxicillin and clavulanic acid (Neo-duplamox, Procter & Gamble, Rome, Italy) with the dosage of 1 g twice a day, starting 1 day prior to surgery and continuing until 8 days post-surgery.

At the time of surgery, patients were asked to rinse with 0.12% chlorhexidine gluconate (Parodontax 012, Stafford Miller, Milan, Italy), and this was continued twice a day for 14 days after the operation. The surgical procedures were carried out essentially as described by Boyne and James³⁰ with minor modifications. After a first palatal incision and 2 vertical releasing incisions, a full-thickness flap was raised and the lateral wall of the maxillary sinus was exposed. A rectangular osteotomy with rounded corners was made, the bony window was fractured, and the sinus mucosa was carefully lifted up to create space for

the placement of the graft material (Fig 1). The bone window was left attached to the mucosa and elevated, with the intent of using it as part of a new roof and to support the Schneiderian membrane, both during the surgery and during the healing phase. After membrane elevation was achieved, sterile MGCSH (Surgiplaster, Class Implant, Rome, Italy) was placed in the sinus, carefully filling the area to receive the implants (Fig 2). The implants, plasma-sprayed screws (Bioblock), were placed immediately where at least 5 mm of crestal bone were present for obtaining primary stability (16 implants). For patients in whom less bone was present, implant placement was postponed until 6 months after the augmentation procedure (14 implants) (Table 1).

Implants were placed following a standard protocol reported by De Leonardis et al.³¹ After the grafting procedure was completed and the calcium

Augmentation + implants										2 nd Stage Surgery		Prosthetic Delivery			
0										9		12			
1 2 3 4 5 6 7 8															
Immediate implants															
OPT										OPT		OPT			
+PR										+PR		+PR			
Augmentation										Implants		2 nd Stage Surgery		Prosthetic Delivery	
0										6		15		18	
1 2 3 4 5										7 8 9					
Delayed implants															
OPT										OPT		OPT			
+PR										+PR		+PR			

Fig 3 Timetable of implant placement and radiographic examinations. OPT = orthopantomographic radiographs; PR = periapical radiographs.

sulfate set sufficiently, the flap was sutured back with nonresorbable sutures (Ethibond Excel, Ethicon, Pratica di Mare, Rome, Italy).

Implants were uncovered and healing abutments were connected 9 months after the placement of implants simultaneously with the augmentation procedure, and 6 months after implant placement according to the staged approach (Fig 3). The implants were restored 12 months after placement, regardless of whether placed immediately or in a staged fashion (Fig 3). All patients were rehabilitated using porcelain-fused-to-metal cemented prostheses. Histologic samples were harvested in the bone window area either 6 months after the augmentation procedure, at the time of implant placement (in patients for whom the implant placement had to be delayed), or 9 months after the augmentation procedure, at second-stage or uncovering surgery (patients for whom the implants had been placed immediately).

Examinations. The implants were examined clinically on a monthly basis following the uncovering procedure until the final restoration was placed, and every 6 months thereafter. Several clinical and radiographic parameters were measured. Clinical parameters measured included:

1. Implant mobility. This was determined using the handles of 2 metal instruments. In the controls done subsequent to prosthesis placement, the restoration was removed on a regular basis to assess implant individual mobility.
2. Probing depth (PD). The depth of the peri-implant sulcus was measured with a hand pressure-sensitive plastic probe (TPS Probe, Ivoclar,

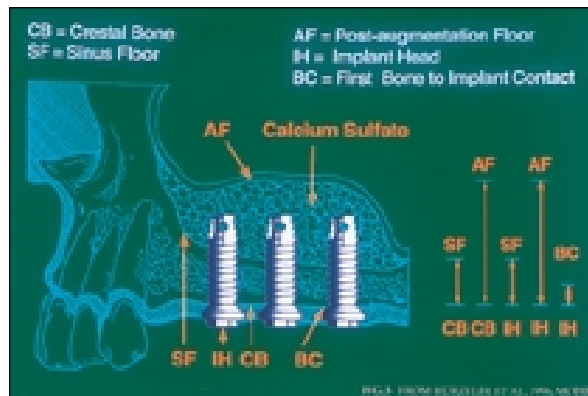


Fig 4 Distances measured on radiographs (modified from Hurzeler et al³²).

Vivadent, Amherst, NY) on the mesial, distal, midpalatal, and midbuccal aspect of each implant.

3. Clinical attachment level (CAL). The distance between the bottom of the sulcus and the shoulder of the final abutment was measured with the same tool and at the same sites as PD (used in the follow-up subsequent to the definitive prosthesis placement; data not reported in the present article).

Radiographic examinations proceeded as follows. Panoramic radiographs were taken prior to the sinus augmentation operation, at implant placement (if staged with respect to augmentation), at abutment connection, at completion of the restoration, and then annually. Periapical radiographs were taken prior to augmentation surgery, on a monthly basis between months 1 and 9 following surgery, after 12 months (for implants placed simultaneously) or 15 and 18 months (for implants placed in a staged fashion) (Fig 3) and at yearly intervals thereafter. The radiographs were used to measure the following distances: between crestal bone (CB) and the sinus floor (SF) prior to and after surgery (AF), between the implant head (IH) and AF, between IH and SF, and between IH and the first bone-to-implant contact (BC) in the extent of the mass of grafted material and its changes over time. Measurements were adjusted to accommodate distortion as well as enlargement, which was possible because of the known dimensions of the implants (Fig 4).³²

Test Group. This group included 45 patients, of whom 5 were treated bilaterally, providing a total

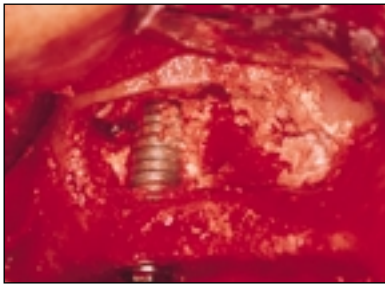


Fig 5 Careful stratification and compaction of calcium sulfate is performed within the sinus and around the implant (test group patient).

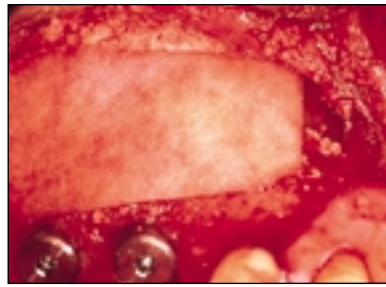


Fig 6 Access window is covered with a collagen barrier (Biomend, Calcitek).



Fig 7 Struts made of prehardened calcium sulfate are used as poles to maintain the space in a sinus in which implants could not be placed simultaneously.

of 50 sinuses. There were 25 males and 20 females, whose ages ranged from 28 to 69 years, with a mean age of 52. They were selected after evaluation of complete medical history and a radiographic examination, as described for the pilot group. Preoperative medications and surgical procedure were the same as for the pilot group, with the following exceptions:

- Calcium sulfate was applied only when it had a putty consistency.
- Special attention was given to careful material stratification; the first layer was compacted with a dry gauze against the bony walls for approximately 1 minute to achieve good hemostasis. Subsequent layers of material were packed and allowed to harden in an environment that was as dry as possible (Fig 5). Fast-setting solution was used to speed the material set and achieve the hardest consistency possible.
- A resorbable barrier (Biomend, Calcitek, Carlsbad, CA) was placed on the outer surface of the graft material, on the lateral window, prior to flap suturing (Fig 6).
- Whenever simultaneous implant placement was not possible because of limited residual crestal bone, poles made of preset calcium sulfate were used to keep the sinus membrane elevated (Fig 7). The poles were created by modeling the calcium sulfate to make cylindrical struts that were approximately 5 mm in diameter and 13 mm in height. The material was then allowed to set completely (for at least 15 minutes) prior to placement in the patient's mouth. When needed, the poles were trimmed to the desired size and shape for accommodation within the sinus.

Treatment schedule times were the same as for the pilot group. All implants were restored with porcelain-fused-to-metal prostheses, cemented 12 months following implant placement, regardless of whether the implants had been placed immediately or with a staged approach.

Since a histologic study is being conducted concurrently, samples were harvested 6 or 9 months after implant placement from the window area and/or from the crest. One hundred implants were placed (Table 1); 75 were titanium plasma-sprayed screws (Bioclock), and 25 were HA-coated screws (Maestro, Biohorizons). Forty implants were placed simultaneously, and 60 were placed according to the staged approach.

Examinations. The observation time and procedure were the same as for the pilot group. The clinical and radiographic parameters were the same as well.

Clinical and Radiographic Results

Clinical results are summarized in Tables 1 and 2; radiographic results are summarized in Table 3.

Pilot Group. The graft material showed a centripetal resorption trend that was generally easily detectable on the 1-month radiographs as a black ring at the periphery of the grafted material. At the 2- and 3-month radiographic examinations, the resorption area was larger and larger, but its radiolucency diminished progressively. Between the second and third months, a radiopaque layer appeared from the periphery following the same pattern of calcium sulfate resorption. On the 4-month radiographs, a new trabecular design, starting from the periphery of the grafted area and having, again, a centripetal fashion, became generally visible.

Table 2 Tissue-related Clinical Results

	Pilot group	Test group	Total
Soft tissue incleftations at the lateral window level	10	4	14
Membrane perforations	2	5	7
Graft "shrinkage" (mm)	6 (2 to 10)*	2.5 (1 to 4)*	—
Peri-implant probing depth (mm)	3.0 ± 0.2	2.8 ± 0.3	—
Peri-implant crestal bone loss (mm)	1.0 ± 1.0	0.8 ± 0.8	—

* Average and range values.

Table 3 Radiographic Measurements in Millimeters

	Pilot group			Test group		
	Presurg	Postop	1-year	Presurg	Postop	1-year
SF/CB	3.5 ± 3	—	—	4 ± 3	—	—
AF/CB	—	18 ± 2	12 ± 2	—	18.5 ± 1	16 ± 1
SF/IH	—	3.5 ± 3	—	—	4 ± 3	—
BC/IH	—	0	1.0 ± 1.0	—	0	0.8 ± 0.8

Presurg = presurgical measurement; Postop = postoperative measurement; 1-year = 1-year postsurgical measurement; SF = sinus floor prior to surgery; CB = crestal bone; AF = sinus floor after surgery; IH = implant head; BC = first bone-to-implant contact.

Between 5 and 6 months postsurgery, the grafted material became radiographically invisible and was replaced by a newly formed trabecular design (Fig 8). During the overall resorption process, the volume of grafted material showed a reduction of 6 mm on average, ranging from 4.5 to 9 mm.

At the time of re-entry surgery, when the regenerated tissue was drilled for implant placement and/or histologic sample harvesting, it showed good consistency (varying between Types II and III bone) for areas augmented either 6 or 9 months earlier. During the re-entry operation, an invagination of soft tissue was found at the access window level in 10 of 15 sites. The depth of this incleftation varied between 1 and several mm, and at times it reached the Schneiderian membrane.

Two minor perforations of the sinus membrane occurred during the augmentation surgeries. They were treated by placing a collagen barrier (Biomed, Calcitek) to seal them prior to graft placement. No infections or other adverse reactions were noted during the entire follow-up reported in the present study. One implant of the 30 placed in this group was not integrated at stage 2 surgery. It had been placed simultaneously with the augmentation procedure. All remaining 29 implants (96.7%) were integrated and considered to be successful at the 12-month examination, according to

the criteria reported by Albrektsson et al in 1986.³³ The vertical bone loss (change in distance between HI and BC) was 1.0 ± 1.0 mm on average during the first year of postimplantation observation. Mean probing depth was 3.0 ± 0.2.

Test Group. At the radiographic examination, the centripetal resorption process of the grafted material seemed to start between the first and second months, being more evident at the second month (Figs 9a and 9b). The radiopaque layer that progressively reduced the radiolucency of the peripheric resorption area appeared between the third and the fourth month following the operation (Fig 9c). In the 5-month radiographs, a new trabecular design appeared from the periphery of the grafted area. On the 6-month radiograph, the graft material was no longer detectable, while the augmented area was filled by new tissue showing an irregular trabecular design (Figs 9d and 9e). The overall healing picture seemed to follow closely that seen for the pilot group, though it was approximately 1 month slower. The "shrinkage" of the grafted material during resorption was 2.5 mm on average, ranging from 1.5 to 3.6 mm (Table 3).

At the time of re-entry surgery 6 to 9 months following augmentation surgery, the regenerated tissue in the window area showed good consistency (varying between Type II and Type III bone).

Fig 8a Preoperative panoramic radiograph showing the edentulous ridge and the enlarged sinuses of a patient of the pilot group.

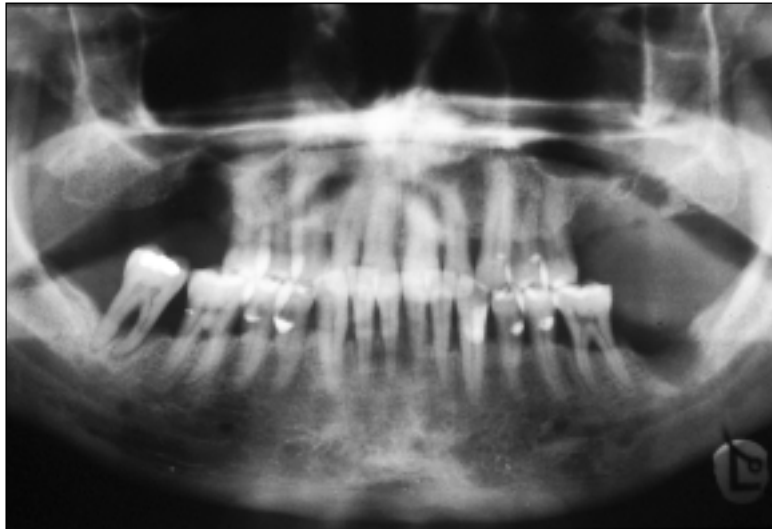
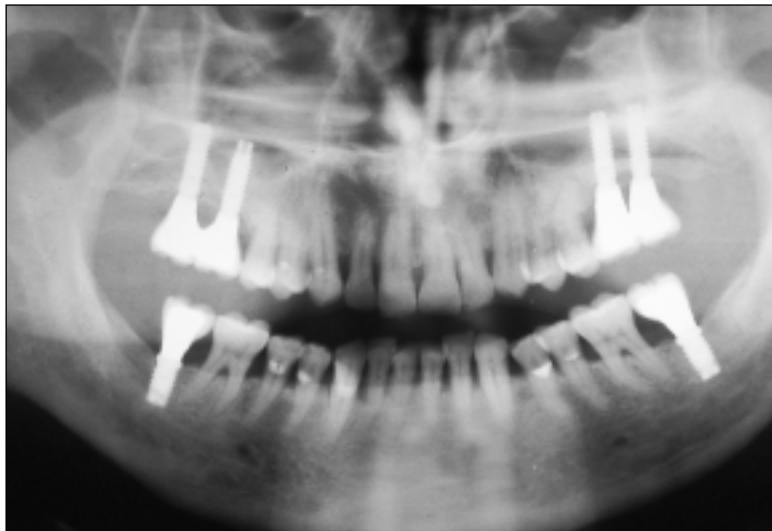


Fig 8b Twelve-month postoperative radiograph demonstrating the 2 augmented sinuses with 2 implants each placed simultaneously with the calcium sulfate.



Invagination of soft tissue at the access window level was found in 4 patients; it measured 2 to 4 mm in depth and never reached the sinus mucosa or the implant surfaces. Five minor perforations of the maxillary sinus mucosa occurred during the augmentation surgeries. They were treated with placement of a collagen barrier. One implant (a plasma-sprayed screw) failed during the prosthetic phase, while the remaining 99 implants (99%) were successfully integrated at the 12-month examination, according to the above-mentioned criteria.³³ The average crestal bone loss (change in distance between HI and BC) 12 months after implantation was 0.8 ± 0.8 mm. Mean probing depth measured 2.8 ± 0.3 mm.

Discussion

The present study supports the efficacy of MGCSH as a grafting material for maxillary sinus augmentation. The clinical and radiographic evaluation showed that it is possible to achieve the formation of new tissue that is quantitatively and qualitatively suitable for endosseous implant placement. The observation drawn from the pilot group also confirmed the concerns of Pecora et al²⁹ concerning possible quick resorption and “shrinkage” of the grafted material during healing. Suggesting that the 2 phenomena may be linked together, the authors of the present study introduced some modifications in the operative technique of the “test group” aimed to

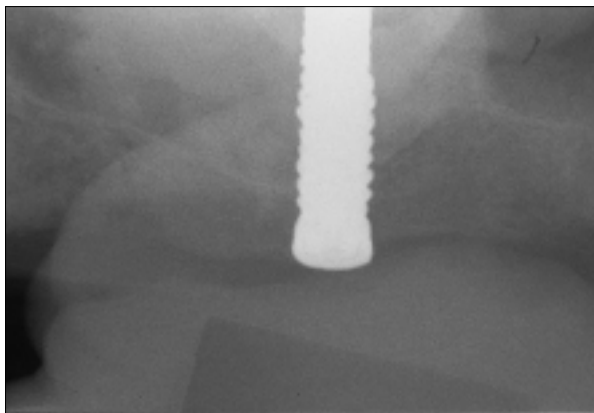


Fig 9a Periapical radiograph taken immediately after sinus augmentation and implant placement (test group patient).

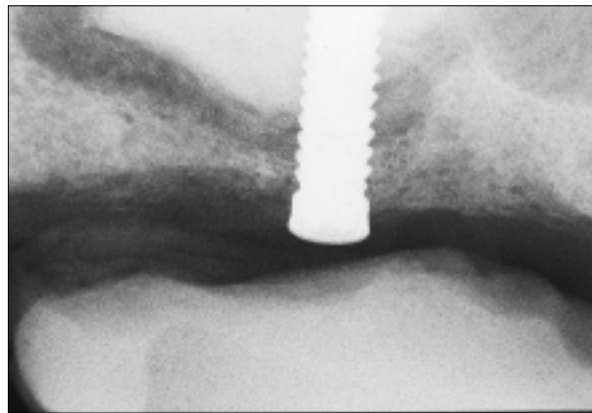


Fig 9b Two-month postoperative radiograph showing peripheral centripetal resorption of the graft material.

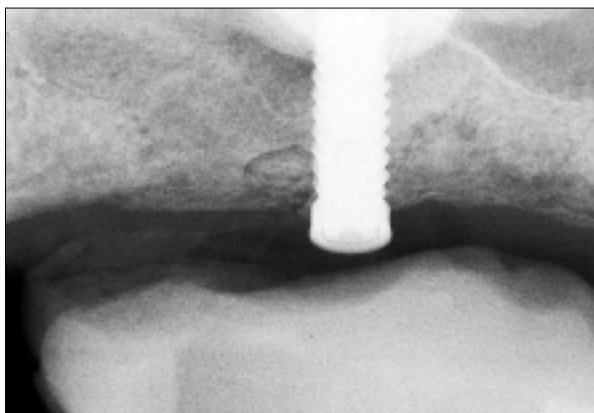


Fig 9c Periapical radiograph taken 4 months after the augmentation procedure, revealing a progressive reduction of the peripheral radiolucency.

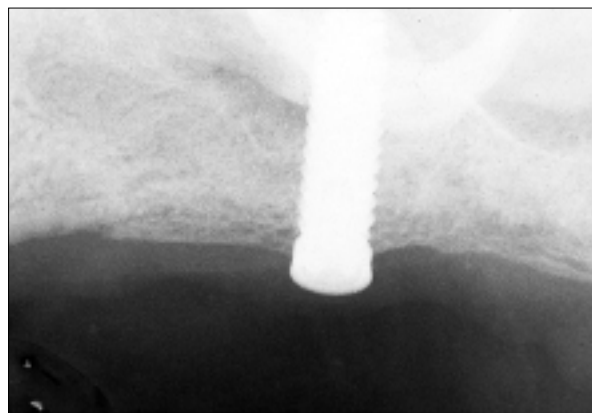


Fig 9d Five-month postoperative radiograph showing the presence of an irregular trabecular design in the previously grafted area.

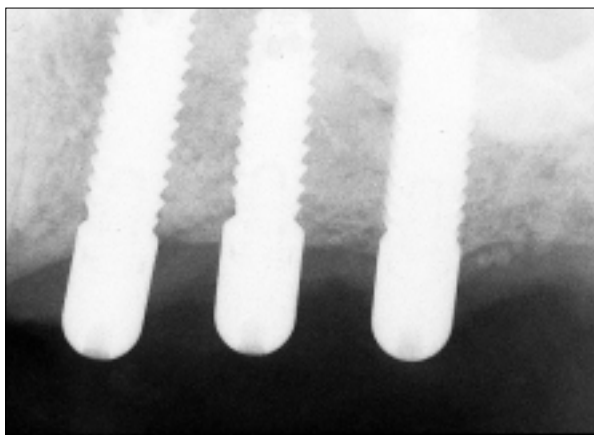


Fig 9e Radiograph taken after the placement of 2 more implants, performed 6 months after the augmentation surgery.

retard the resorption process, thus minimizing the volume reduction of calcium sulfate. In this regard, the creation of a solid mass of MGCSH without voids was achieved through the application of the material in a putty consistency and careful compacting in conditions that were as dry as possible. Comparison of the radiographs between the pilot and test groups confirmed that in the second group, a general slowing of the phases of MGCSH resorption and replacement with new tissue had taken place. At the same time, the average reduction in mass of the grafted material shifted from 6 mm in the pilot group to 2.5 mm in the test group. This confirmed both the relationship between time of resorption and graft material reduction in mass during healing, and the possibility of controlling these factors by material condition at the time of placement.

Interesting data emerged from the study regarding the complete resorption of calcium sulfate within a 9-month period, and usually within 6 months. These results are encouraging, in that it is the final goal of the grafting procedure to achieve formation of 100% living tissue surrounding the implants. In fact, the presence of a reactive tissue able to undergo a sustained state of remodeling may be the condition necessary to maintain the osseointegration over time.³⁴ In addition, according to the present results, it would appear that it is not absolutely necessary to harvest autogenous bone to attain good results with the sinus augmentation procedure. Calcium sulfate seems to be a viable alternative to other bone substitutes, such as DFDBA or HA, whose resorption and remodeling trends are slow and unclear.^{16,22-24}

Only one of the 130 implants placed into the augmented sinuses failed to osseointegrate, and another lost osseointegration during the prosthetic phase, yielding an implant success rate of 98.5% during the first year of follow-up. This percentage is similar to the high success rates reported in previous studies for implants placed in the maxilla without sinus augmentation, in both completely³⁵ and partially edentulous patients.^{31,36} These results seem to be definitely positive, although they should be interpreted with caution, since the role played by the residual alveolar crest in determining the clinical success of implants placed within augmented sinuses is not completely clear and cannot be assessed from this study. The 1-year crestal resorption was 1.0 ± 1.0 mm for the pilot group and 0.8 ± 0.8 mm for the test group. The above results match well the average values reported by Adell et al.³⁷ Among the complications identified by the pilot group experience was the soft tissue invagination at the level of the access window. That issue seemed to be almost completely addressed in the test group through the use of a collagen barrier for guided tissue regeneration placed on the graft material. Complications were rare, even in the case of a sinus membrane tear (1 case of infection in 7 total perforations), and that could have been the result of an appropriate surgical technique, antibiotic coverage, and/or the biological characteristics of MGCSH.

Conclusion

The results of the present study support the efficacy of MGCSH as grafting material for maxillary sinus augmentation. Moreover, the possibility of improving the clinical behavior of the material by modifying the technique of application has also

been shown. Other ways to enhance MGCSH performance may be the use of preset forms of material and its use in combination with other substances such as antibiotics or stimulating factors.

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