
Short-Term Healing Following the Use of Calcium Sulfate as a Grafting Material for Sinus Augmentation: A Clinical Report

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Because of the frequent lack of bone in the posterior maxilla, sinus augmentation has become a commonly practiced treatment modality. Many different materials have been used for augmenting the sinus, and the ideal graft is yet to be found. The present article reports the results of sinuses grafted with calcium sulfate in 2 patients. Bone biopsies were harvested 9 months after the augmentation procedure. In the first patient, 3 titanium threaded-cylinder implants were placed in the grafted area after 9 months, while in the second, 1 acid-etched, screw-shaped titanium implant was placed simultaneously with the graft. Light microscopic evaluation revealed new bone formation with ongoing remodeling and progressive lamellar maturation in the specimens. No remnants of the alloplastic material were detectable in any section, either within the bone or in the medullary tissue. When reevaluated at the uncovering procedure, the implants were radiographically and clinically judged to be osseointegrated. These observations suggest that, when used in the appropriate form and with the proper technique, calcium sulfate is a promising graft material for sinus augmentation, producing adequate quantity and quality of new bone for implant placement.

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The predictability of osseointegrated implants in the treatment of both partially and completely edentulous patients with sufficient bone quantity has been well documented.^{1,2} The posterior maxilla is an area commonly requiring dental implants for oral rehabilitation, since maxillary molars are often lost

because of periodontal failure.³ Alveolar bone loss after tooth extraction and sinus pneumatization may result in insufficient bone for implant placement. In selected patients, sinus augmentation (often referred to as "maxillary antroplasty") can be an effective treatment option. Alternative approaches include a Le Fort I osteotomy and interpositional iliac bone graft⁴ or onlay grafting with iliac crest bone.⁵

The sinus lift procedure was first described in 1977 by Tatum,⁶ who used an alveolar crestal approach. In 1980 Boyne and James introduced the lateral osteotomy.⁷ Since these procedures were introduced, the technique has been modified several times.⁸⁻¹⁰ Sinus augmentation may become difficult if unusual anatomy, such as a septum in the sinus floor, is present. Some modifications in the surgical technique have also been proposed for managing unusual sinus anatomy, such as a septum in the sinus floor,¹¹ and for stabilizing autogenous cancellous bone grafts.¹² Different materials have been used for sinus grafting. Among those commonly used are autogenous bone,^{7,9,13-16} mineralized or demineralized bone

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Fig 1 Radiographic appearance of patient #1 with a failing fixed prosthesis.



allografts,¹⁷⁻¹⁹ hydroxyapatite,^{8,16,20-22} and a variety of combination grafts.^{16,22-24} Even though reports suggest that bone augmentation within the maxillary sinus can be obtained using different graft materials, it is not yet evident which can be considered the material of choice. This is partly the result of the ethical and technical difficulties involved in testing new materials and the retrieval of specimens adequate for evaluation in humans.

Autologous grafts are currently considered the gold standard, in terms of osteogenic potential, against which other materials are compared.^{7,9,13-16} The disadvantages of autogenous grafts include: (1) a limited amount of material is available¹⁶; (2) morbidity is sometimes encountered at the donor site; and (3) general anesthesia is required for extraoral bone harvesting.^{16,25} An interesting alternative is demineralized freeze-dried bone (DFDB), introduced by Urist in 1965²⁶ and recently used for sinus augmentation.^{16,17,23,24,27} Current findings²⁸ seem to question the efficacy of DFDB for predictable implant placement in the augmented sinus because of its slow and unclear remodeling trend and insufficient production of high-quality bone. Thus, the ideal graft material is yet to be realized. Criteria for selection of material for sinus augmentation include the following, suggested by Block and Kent in 1993.²⁹

1. Efficacy of bone formation in the sinus
2. Capability of stabilizing the implants when placed simultaneously
3. Low risk of infection
4. Ease of availability
5. Low antigenicity
6. High level of reliability

Another desirable characteristic seems to be complete reabsorption of the material in a clinically reasonable time. As reviewed by Peltier in 1961,³⁰ plaster of Paris (calcium sulfate) was one of the first bone substitutes to be used by Dreesman (in 1982). In subsequent studies, Peltier³⁰ and Peltier et al³¹ noted normal bone regeneration and complete resorption of plaster, with no measurable rise in serum calcium level, when calcium sulfate was used. Other authors reported that following the use of calcium sulfate, complete bone regeneration occurred in approximately 3 months in dogs³² and that regeneration of normal bone was achieved earlier than with autogenous grafts.³⁰ While Cotzee³³ stated that when calcium sulfate is placed in contact with bone or periosteum, bone regeneration is accelerated, McKee and Bailey³⁴ found that successful replacement of this alloplastic material by normal bone occurred both with and without the presence of periosteum. Finally, calcium sulfate has been proposed as an effective binding and stabilizing agent for particulate graft materials.³⁵

The present patient reports describe the clinical and histologic evaluation of medical-grade calcium sulfate hemihydrate (MGCSH) as a grafting material for maxillary sinus augmentation prior to, or in combination with, implant placement.

Patient 1

A 50-year-old female presented with a failing maxillary fixed prosthesis supported by natural teeth and 1 implant (Fig 1). Computerized tomography (CT) and conventional panoramic radiographs showed insufficient bone height and width for the placement of

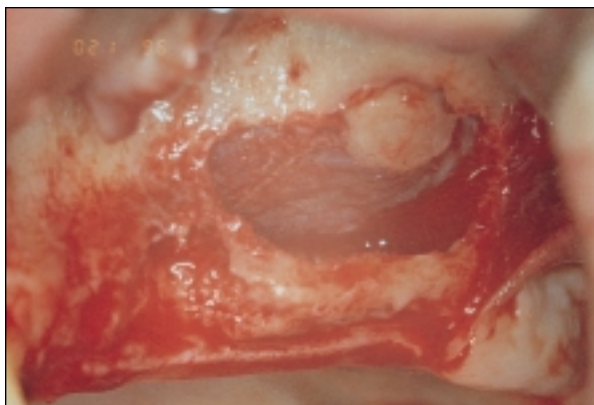


Fig 2 After flap elevation the bony window is outlined.

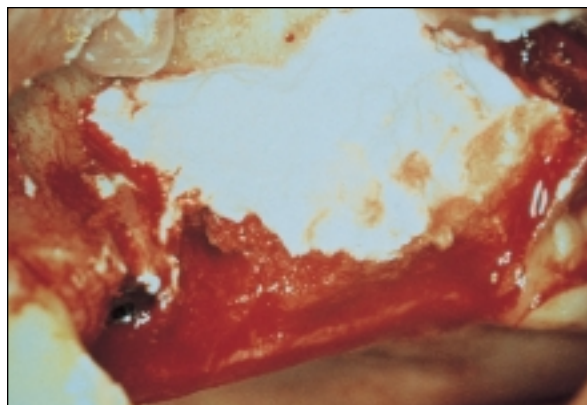


Fig 3 Calcium sulfate overfilling the sinus.

root-form implants. The patient did not smoke and was in good health. Her medical history was negative for sinus pathology. After a thorough presurgical evaluation, including study of the mounted casts and a diagnostic wax-up, treatment was planned to include monolateral sinus elevation with simultaneous placement of 1 implant in the position of the maxillary first premolar, followed by the staged placement of 3 more implants. The staged placement of the 3 implants was decided upon because of the lack of sufficient bone to stabilize the implants in the most distal area. The most mesial implant was to be immediately placed because there was enough bone for primary stability and thus the sinus membrane could be kept elevated during the healing phase.

The patient accepted the treatment plan and, following the removal of the failed implant and teeth, a healing period of 1 1/2 months was allowed to provide complete soft tissue closure. Following healing, a palatal incision was made and a flap was raised, split thickness for the first 3 mm, then full thickness on the ridge crest and buccal surface. In addition, 2 vertical releasing incisions were made to improve access to the lateral sinus wall. A round diamond 4.0-mm high-speed bur was used to outline an oval-shaped osteotomy of approximately 8 × 12 mm. The lateral wall of the maxilla was then fractured inward and upward (Fig 2) and the sinus membrane was gently lifted, using care not to tear it. The bony window was used to create a kind of roof for the graft material. MGCSH (Surgiplaster, Class Implant, Rome, Italy), puttylike in consistency, was used as the graft material (Fig 3). Considerable attention was given to the mixing and grafting technique. A first mixing, puttylike in consistency, was carried to the medial sinus

wall and packed with wet gauze. A second application was delivered to the medial wall to completely fill half the sinus width. Following the placement of a titanium implant 13 mm in length (Screw Vent, Dentsply, Encino, CA) in the most mesial area of the sinus, the remaining sinus cavity was obliterated up to the outer surface with MGCSH as high as 15 mm. The material was overextended on the lateral wall, and a gauze wet with fast-setting solution was applied to smooth and harden the graft (Fig 3). Vertical mattress and interrupted sutures (Gore-Tex, Gore and Associates, Flagstaff, AZ) were placed to completely close the flap. Amoxicillin and clavulanic acid (Neo-Duplamox, Procter & Gamble, Rome, Italy) were prescribed at the dosage of 1 g twice a day for 7 days, along with oral rinses with chlorhexidine digluconate 0.12% (Dentosan, Raffaello Pagni, Florence, Italy) for 21 days.

Periapical radiographs were obtained at baseline and 1 month, 3 months, 6 months, and 9 months after surgery and panoramic radiographs were taken 9 months after surgery (Fig 4). When compared with the presurgical radiographs, these showed an increase in bone quantity. Nine months after augmentation, the site was reentered, and 2 bone cores, 3.5 mm in width and 7 mm in height, were harvested for histologic evaluation in the area where the window had been infractured (Fig 5). Three implants were then placed, measuring 13 mm, 10 mm, and 13 mm in length, respectively (Fig 6). All 4 implants were reexamined 6 months later, at the time of stage II surgery (uncovering procedure), and they appeared to be both radiographically and clinically osseointegrated according to the criteria for implant success proposed by Albrektsson et al in 1986.³⁶

Fig 4 Radiograph of the implant and the grafted sinus at 9 months.

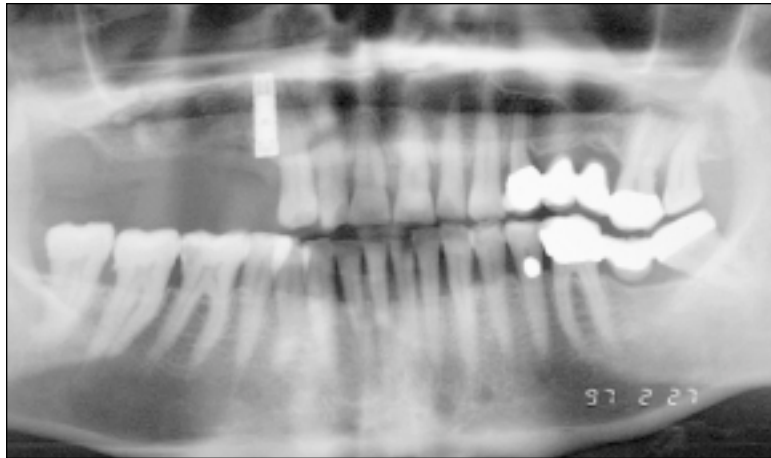


Fig 5 Reentry surgery at 9 months. Note the prepared implant sites on the crest of the ridge and the osteotomy left by the biopsy in the area where the window had been infrafractured and the calcium sulfate had been grafted.

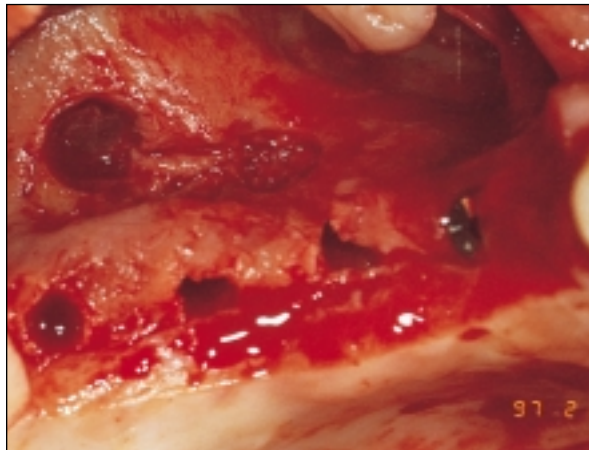


Fig 6 Panoramic radiograph showing the 3 additional implants placed in the augmented sinus.

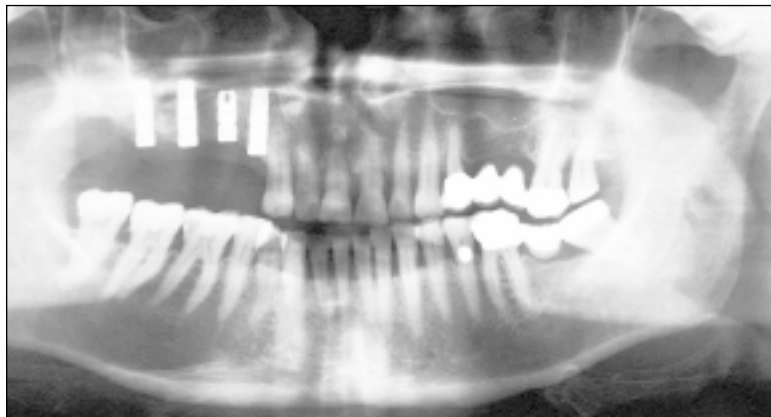




Fig 7 Radiograph of the bone situation in patient #2.



Fig 8 Partial bone window removal and sinus membrane lifting.



Fig 9 Postoperative radiograph of the implant and calcium sulfate graft placed within the sinus under the lifted membrane.

Patient 2

A 35-year-old female presented with a missing left maxillary first molar. The radiographic evaluation showed insufficient bone quantity as well as evident sinus pneumatization, requiring a sinus augmentation procedure for placement of an implant (Fig 7). The patient was neither a smoker nor affected by systemic or sinus disease. Following thorough evaluation and treatment planning, the patient opted for sinus augmentation and simultaneous implant placement. The sinus procedure was performed following the technique previously described—flap elevation, bone window outlining and infracturing, and sinus membrane lifting (Fig 8). In this situation, 1 implant (Bioclock Int Inc, Deerfield Beach, FL) 3.75×13 mm was placed immediately in combination with the MGCSH. Half the graft was placed before and half was placed after implant placement, extending

approximately 3 mm beyond the implant apex (Fig 9). The calcium sulfate was then packed and smoothed until complete fill of the opening was obtained, and firm hardening was induced with the fast-setting solution. Primary flap closure was achieved with mattress and interrupted sutures. Antibiotics and chlorhexidine were prescribed, as with the previous patient.

Periapical radiographs were taken preoperatively and postoperatively and after 1 month, 3 months, 6 months, and 9 months. At 9 months, the site was reentered (Fig 10) and a tissue, which appeared to be cortical bone, presenting a small residual concavity, was found where the window had been opened during stage I surgery. A bone biopsy was harvested close to the concavity penetrating to at least 7 mm in the newly-formed tissue. The implant was clinically osseointegrated, and the 9-month radiograph highlighted the formation of a radiopaque tissue that surrounded the implant body, leaving the apical portion exposed (Fig 11). These findings suggested effective tissue augmentation but also some shrinkage of tissue during the alloplast resorption process.

Histology

Materials and Methods. The bone specimens were fixed for at least 2 hours in 4% formaldehyde buffered in phosphate buffer (pH 7.2) and then were treated without decalcification for glycolmethacrylate embedding. From the blocks, 2- μ m consecutive thick sections were obtained and stained with hematoxylin and eosin and methylene blue-azure II methods.

Results. Cellular and matrix components were detectable in the 2- μ m-thick undecalcified sections. Noncalcified osteoid tissue was easily differentiated from normally calcified bone, permitting the remodel-



Fig 10 The site at the reentry operation 9 months later. Note the partial bone enucleation and the bone core being harvested for histologic evaluation.

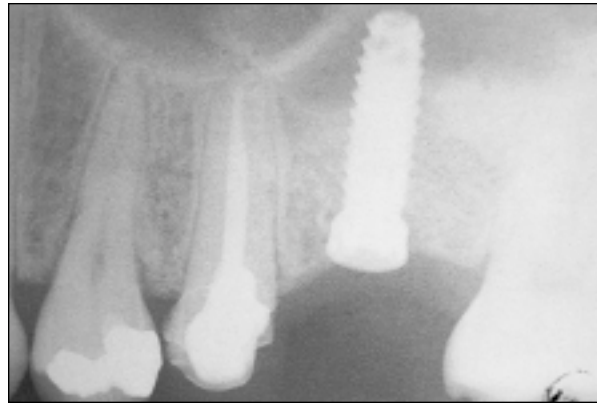


Fig 11 Radiograph of the implant and the augmented bone 9 months after antroplasty. Note that at least 10 mm of new bone has formed (compare to Fig 9), while the apex of the implant is not surrounded by radiopaque tissue.

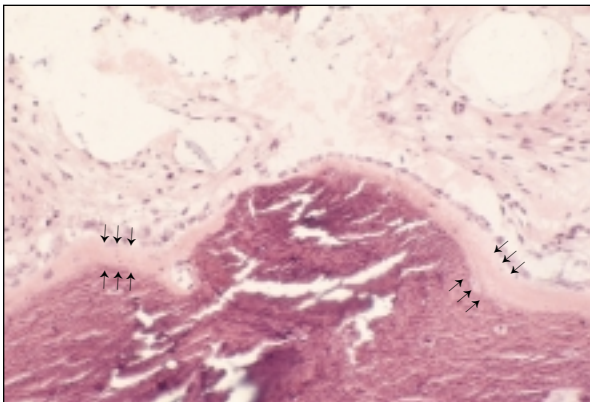


Fig 12 Bony trabeculae are lined by thick, noncalcified osteoid tissue between the arrows; no foreign material is detectable in the marrow (hematoxylin-eosin; original magnification $\times 25$; undecalcified section).

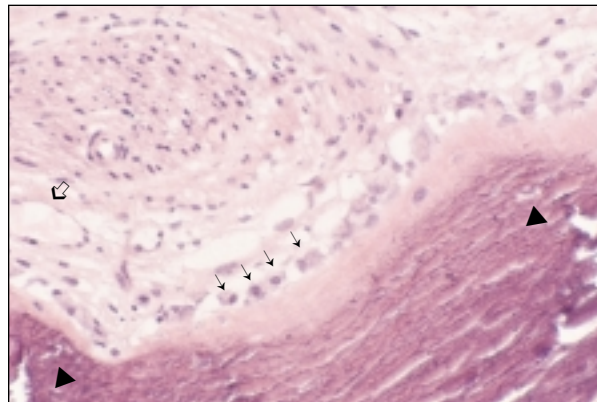


Fig 13a Active osteoblasts (*arrows*) are clearly detectable lining osteoid tissue, while some plump osteocytes (*arrowheads*) are present in the calcified trabeculae, indicating the woven arrangement of the bone. Dilated vessels (*open arrows*) are present in the marrow (hematoxylin-eosin; original magnification $\times 40$; undecalcified section).

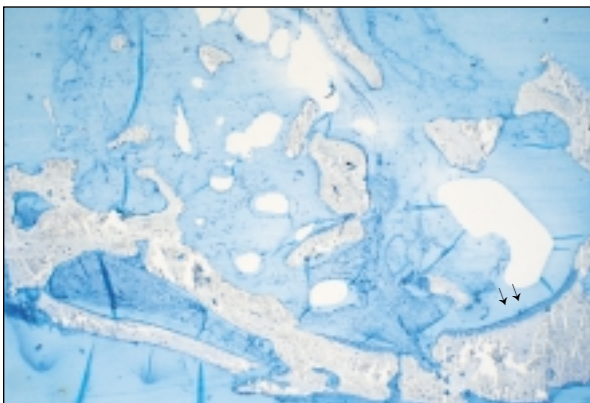


Fig 13b A few borders show augmented osteoid tissue (*arrows*), and the trabecular arrangement of the bone is evident (methylene blue-azure II; original magnification $\times 10$; undecalcified section).

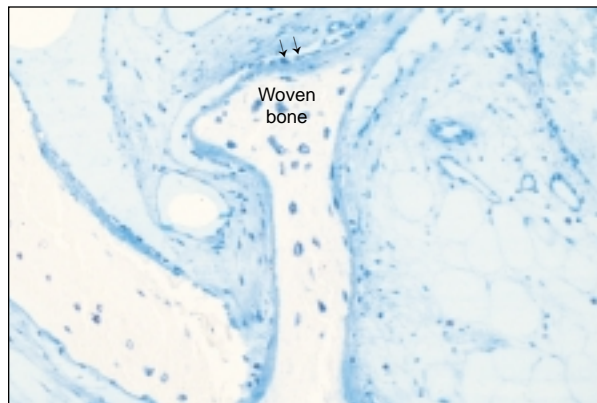


Fig 14 Occasionally, trabecular bone of the woven type can be observed (labeled), and active osteoblasts (*arrows*) are present lining the osteoid tissue. The marrow is adipose (methylene blue-azure II; original magnification $\times 25$; undecalcified section).

ing phenomena to be recognized without any difficulty (Fig 12). Both specimens featured trabecular bone with woven and lamellar architecture, the latter being more prominent in the second specimen (Figs 13a and 13b). Remodeling was present mainly in the first specimen, although osteoblastic borders and rare resorption cavities were also present in the second specimen (Fig 14). No inorganic or foreign substance was detected in the marrow, which featured adipose tissue and normal vessels. All these findings suggested new bone formation with progressive lamellar maturation.

Discussion

Results of the above illustrated treatment situations show that it is possible to achieve sinus bone augmentation with the use of a medical grade calcium sulfate hemihydrate (MGCSH) as the only graft material. The histologic analysis provided evidence of newly formed bone featuring noncalcified osteoid tissue and ongoing bone remodeling. The overall picture is of trabecular bone with woven and lamellar architecture. The latter was more evident in the second specimen, although signs of remodeling were present. The medullary spaces were filled by adipose marrow with normal blood vessels. No remnants of alloplastic or foreign substances were detected in any field, suggesting that complete resorption of the calcium sulfate had occurred 9 months after the augmentation procedure.

Demineralized freeze-dried bone (DFDB) has yielded variable results,^{16,17,23,27,37} and some authors have reported poor quality and quantity bone formation in augmented sinuses using DFDB.^{17,28,38} The sinuses augmented with autogenous bone exhibited more desirable characteristics for implant placement.²⁸ However, autogenous grafts have limitations such as a limited amount of available material,¹⁶ donor site morbidity, and the need for general anesthesia to harvest extraoral bone.^{16,25} In addition, the cortical portion of autogenous grafts seem to undergo a questionable turnover process after grafting, which may last for years.³⁹ The presence of cortical bone in part or the majority of the autologous graft may not create the most favorable scenario for long-term implant survival, because the biologic objective is to have newly formed live bone adjacent to the implant surface.

Other authors have used nonresorbable hydroxyapatite for sinus augmentation with or without DFDBA.^{8,16} Nonresorbable hydroxyapatite has been found to be unsatisfactory for bone augmentation since it is purely osteoconductive, has no osteoinductive power, and does not integrate with implants.^{21,40} Successful sinus lifts with bovine bone³⁸ and resorbable hydroxyapatite, alone or coupled with

DFDB,^{8,21,24} have been reported. But the actual resorption of hydroxyapatite is currently under scrutiny and some authors have suggested that it produces inconsistent results, with minimal amounts of new bone, and there is no evidence that it increases the loading capability of the implants.⁴¹ For these reasons, alternative materials for bone augmentation are being tested.

Calcium sulfate seems to be promising because of its long history of safe use³⁰ and its characteristic complete resorption followed by bone formation.³⁰⁻³⁴ In the patients described in the present article, while bone augmentation was evident both radiologically and clinically, no calcium sulfate was detected in the histologic sections, suggesting complete resorption of the grafted alloplast and its subsequent replacement by newly formed bone. The radiologic observations were consistent with these findings, even though partial reduction of the calcium sulfate bulk was detected, based on the subjective comparison of the pre- and postsurgical radiographs.

Conclusion

Clinical and histologic observations from the treatment of the 2 patients presented suggest that calcium sulfate seems to be a viable material for sinus grafting. Additional investigations are necessary to understand the actual pattern, timing, and volume reduction during resorption and the eventual possibility for retarding such a process. Moreover, it may be interesting to evaluate the combination of MGCSH with other graft materials to determine whether it is possible to take advantage of the positive characteristics of 2 or more substances.

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