

Calcium Sulfate as a Bone Grafting Material in Sinus Lift Augmentation – A Literature Review

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ABSTRACT

Purpose: The purpose of this paper is to analyze the literature for the use of calcium sulfate (CS) as a grafting material in maxillary sinus lift procedure. **Materials and Methods:** An online literature analysis was done using PubMed, MEDLINE, and Google Scholar for the studies reporting the use of CS alone or in combination with other bone substitutes used in maxillary sinus elevation surgery until April 21, 2021, using relevant keywords. **Results:** Analysis showed that the prognosis of the maxillary sinus lift procedure was best when CS was used as a grafting material. Rapid resorption of CS can be slowed down using CS in a putty consistency without voids, careful CS stratification, and using fast setting solution to speed the setting time of CS and to achieve the hardest consistency possible. **Conclusion:** CS can be used successfully as a grafting material in both the internal and external maxillary sinus elevation techniques either used alone or in combination with other graft materials.

Key words: Calcium sulfate, biphasic calcium sulfate, medical-grade calcium sulfate hemihydrate, maxillary sinus

INTRODUCTION


In this current era, the best available option to replace missing tooth/teeth is dental implants, however, this option is not always available without site preparation before implant placement. An example of site preparation before implant placement is maxillary sinus lift augmentation which is indicated to manage maxillary sinus floor pneumatization and alveolar ridge resorption which resulted due to natural sequence of teeth loss. Maxillary sinus lift augmentation is a common surgical procedure which is indicated to increase bone volume in order to enable dental implantation in a prosthetically ideal position.

There are two different techniques available for maxillary sinus floor lift: (1) External or lateral window sinus lift and (2) internal or osteotome sinus lift. The internal sinus lift procedure was originally

described by Tatum.^[1] Osteotome (internal) technique was recommended for elevating the sinus membrane when less amount of sinus augmentation (up to 5 mm) is required using crestal/indirect approach which is more conservative in nature as compared to external technique.^[2] However, when the intended sinus membrane elevation height is greater than 5 mm, the recommended technique is external sinus lift which was designed and described by Boyne and James.^[3]

The maxillary sinus augmentation procedure has been well documented, and the long-term clinical success/survival of implants placed, regardless of graft material(s) used, compares favorably to implants placed in native bone with no grafting procedure.^[4] This surgical procedure necessitates the use of bone grafts so as to hold the Schneiderian membrane away from future implant sites. Moreover, the addition of the graft material helps in bone regeneration to increase the vertical dimension.

It is a well-known documented fact that the gold standard of reconstructive surgeries (including maxillary sinus) bone graft is autograft, however, autograft is not considered a viable option for maxillary sinus elevation procedure for several

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reasons.^[5] First of all, it requires additional surgery on the donor site, the graft retrieved too is limited, there is patient discomfort, and relative risk of complications.^[6]

Innumerable alternatives have been developed and used pertaining to autogenous bone grafts in bone regeneration procedures either in medical or dental fields. These alternatives can be categorized as allograft, xenograft, and alloplast (synthetic) based on from where it is harvested. The benefits of synthetic grafts include availability, sterility, and reduced morbidity.^[7] One of the synthetic materials is calcium sulfate (CS) which is an inorganic compound with the formula CaSO_4 , known in the marketplace as gypsum plaster or plaster of Paris.^[8] For approximately 120 years, CS has been used in both medical and dental fields due to its biocompatibility and resorbability.

Depending on the amount of water molecules found within a single molecule unit, CS has three different forms:

1. Calcium sulfate anhydrite (CaSO_4)
2. Calcium sulfate dihydrate ($\text{CaSO}_4 \cdot 2\text{H}_2\text{O}$)
3. Calcium sulfate hemihydrate ($\text{CaSO}_4 \cdot \frac{1}{2}\text{H}_2\text{O}$).

The hemihydrate state of hydration exists as either an α or a β form, both of which are found in medical-grade CS products. When this hemihydrate is mixed with water, a dihydrate is formed in a mild exothermic reaction with crystallization taking place, and the material sets and hardens.^[9]

There are two forms of CS which are commercially available and can be used in bone regeneration procedures:

- Medical-grade CS hemihydrate (MGCSH): The most common form of CS used in bone grafting procedures
- Biphasic CS: It is composed of two phases of highly pure MGCSH and dihydrate.

CS is an osteoconductive as well as bioinert grafting substitute. When CS is used in bone regeneration procedures, it stimulates angiogenesis and improves the new bone formation by providing a direct source of calcium which may help induce the initial stage of osteoprogenitor cell migration more rapidly.^[10,11]

Since 1998, several reports have been published validating the use of CS in maxillary sinus lift surgery. CS is considered as a fast resorbable synthetic material, therefore using this material in maxillary sinus elevation procedure which requires

prolonged healing time lasting up to 6 months may be questionable.^[10,12] The purpose of the present paper was to review the scientific data regarding the use of CS as a grafting material in maxillary sinus lift procedure either as stand-alone grafting material or in combination with other bone substitute by reviewing all published studies that report the use of CS in maxillary sinus lift procedure.

MATERIALS AND METHODS

The authors searched for the research studies reporting the use of CS alone or in combination with other bone substitutes in maxillary sinus elevation surgery through PubMed, MEDLINE, and Google Scholar until April 21, 2021, using relevant keywords such as sinus lift technique, CS, maxillary sinus augmentation, and maxillary sinus elevation and the non-relevant studies not pertaining to the topic were excluded from the present study. In all, 16 studies (one animal study, three case reports, eight case series, and four clinical trials) were found, as summarized in Table 1.

Animal Studies

Only one animal study was found which was conducted on rabbit evaluating the use of CS in maxillary sinus lift procedure. In this study, CS alone was used for the control sites, while sodium butyrate incorporated onto CS was used for the test sites. The immunohistochemical analysis showed mature lamellar bone with degree of mineralization of bone trabeculae in both groups at 4 weeks after the procedure. However, the test group depicted a great amount of mature lamellar bone and a higher level of mineralization of bony trabeculae as compared to the control group. In the radiographic analysis, the total augmented volume of the test group was $158.22 \pm 39.31 \text{ mm}^3$ whereas in the control group was $107.09 \pm 39.69 \text{ mm}^3$. This study concluded that CS can be possibly used as a grafting material for maxillary sinus lift procedures.^[13]

Case Report

A case report delineated by Guarnieri *et al.* was published in 2002 to assess the use of granular MGCSH as a potential grafting material in maxillary sinus lift procedure and was analyzed radiographically and histologically. In this case report, one patient received maxillary sinus lift procedure with CS used as a grafting material. A resorbable membrane was not placed before flap suturing in the site. After 8 months of augmentation, three implants were placed, and

Table 1: Summary of the data retrieved from the research papers included in the present study

Study type	Author name	Year of publication	Type of sinus lift technique	Materials used
Animal	Cha <i>et al.</i>	2017	External	(Sodium butyrate (SB) + CS) versus (CS)
Case series	Pecora <i>et al.</i>	1998	External	CS
Case report	Guarnieri <i>et al.</i>	2002	External	CS
Case report	Iezzi <i>et al.</i>	2007	External	CS
Case report	Mazor <i>et al.</i>	2015	Both	CS+ PRF (external) versus CS (internal)
Case series	Pecora <i>et al.</i>	1998	External	CS
Case series	De Leonardis <i>et al.</i>	1999	External	CS
Case series	Andreana <i>et al.</i>	2004	External	CS versus CS + FDDBA
Case series	Guarnieri <i>et al.</i>	2006	External	CS
Case series	Slater <i>et al.</i>	2008	External	CS
Case series	Dasmah <i>et al.</i>	2012	External	CS
Case series	AlGhamdi	2013	Internal	Bovine bone and CS
Case series	Laino <i>et al.</i>	2015	External	CS
Clinical trial	De Leonardis <i>et al.</i>	1999	External	CS not stratified versus stratified CS
Clinical trial	Scarano <i>et al.</i>	2006	External	Autologous, DFDBA, Biocoral, Bioglass, Fisiograft, PepGen P-15, CS, Bio-Oss, and hydroxyapatite
Clinical trial	Gultekin <i>et al.</i>	2016	External	DBB versus CS and DBB
Clinical trial	Ahmet <i>et al.</i>	2016	External	CS and DBB versus CS and alloplast

CS: Calcium sulfate

the bone biopsy was harvested from the surgical site. The histological results revealed complete resorption of CS and a normal living trabecular bone with a woven and lamellar structure. The analysis of 2-month radiograph revealed that there was a centripetal resorption trend of CS while, in the 5-month radiograph, a new design appeared from the periphery of the grafted site. In the 8-month radiograph, CS was not detectable.^[14]

In another similar case report delineated by Iezzi *et al.*, published in 2007, an immediately loaded provisional implant retrieved 7 months after simultaneous placement in a human maxillary sinus grafted with CS histologically was evaluated. The study revealed that, 7 months after the procedure, the implant retrieved was completely surrounded by native and newly formed bone. Lamellar bone, with small osteocyte lacunae, was present and in contact with the implant surface. At the bone-

implant interface, no gaps or soft tissues were detected. In addition, no residual CS was detected. This case report showed complete resorption of CS at 7 months after procedure and formation of new bone on the surface which was in close contact with the implant surface after immediate loading.^[15]

In 2015, Mazor *et al.* published a case report to evaluate the use of CS in maxillary sinus lift procedure. In their study, a 70-year-old female patient received internal (osteotome) sinus lift on the right side, which was grafted with nanocrystalline CS bone graft using indirect approach. The lateral window sinus lift procedure which is the direct approach was used on the left side, which was then grafted with nanocrystalline CS in combination with platelet-rich fibrin. Implants were placed simultaneously. Computed tomography scans showed bone formation in both the augmented sites at 6 months. The study revealed satisfactory results

with good implant stability which was achieved at 2-year follow-up.^[16]

Case Series

The first clinical report that delineated the use of CS in maxillary sinus lift was published in 1998 by Pecora *et al.* In this clinical report, maxillary sinus lift procedure was performed using CS as a graft material in two patients. Implants were placed 9 months after the grafting procedure, and bone biopsies were harvested for light microscopic evaluation. They found that no sign of CS was detected and there was new bone formation with ongoing remodeling and progressive lamellar maturation in the specimens. This study concluded that CS achieved successful results and is a promising graft material for sinus augmentation, producing adequate quantity and quality of new bone for implant placement.^[17]

Andreana *et al* in 2004, through a retrospective study, evaluated the use of CS alone or in combination with DFDBA for sinus lift procedures histologically and clinically. Six cases were included in this study. CS in combination with DFDBA was used in five cases while one case received CS alone. Bone was harvested for analysis in the site, which was grafted with only CS, and also 6 months after the procedure. While in CS/DFDBA, bone biopsies were harvested at different times ranging from 8 to 24 months. Histological evaluation revealed new bone formation in all samples examined. No residual of CS was present in any samples while remnants of the grafted DFDBA were still detectable at 8 and 12 months. The cases reported indicated that CS can be successfully used alone or in combination with DFDBA for sinus lift procedures.^[18]

In 2006, Guarnieri *et al.* conducted a case series to evaluate the radiographic and histologic results when granular MGCSH was used as a grafting material in sinuses in 10 patients. Fifteen maxillary sinus elevation procedures were performed using granular MGCSH as a grafting material with simultaneous implant placement. Bone biopsies were harvested from all patients for histologic and histomorphometric evaluation 6 months after the procedure. The results revealed that vital trabecular bone with woven and lamellar structure was found in all the examined sections with no inorganic or foreign substances detectable in bone or marrow. This study showed that using CS as graft material in the sinus lift procedure led

to appropriate osseointegration of dental implants and created adequate bone volume for implant placement. Furthermore, they concluded that CS undergoes complete resorption, allowing grafted areas to be replaced by 100% living bone however, the technique of bone harvesting was not mentioned in this study since they placed the implants at the same time of sinus lift procedures. Bone biopsy from the grafted sites 6 months after the sinus lift and implant placement could compromise the stability of implants.^[19]

In 2008, Slater *et al.* performed a maxillary sinus lift procedure using CS as graft material in seven patients. Bone biopsies were harvested from the maxillary sinus 4 months after the procedure. Samples retrieved from seven patients were examined by field emission scanning electron microscopy and energy-dispersive X-ray spectroscopy. The study revealed that remnant graft material was present in isolated areas surrounded by bone and comprised individual particles up to 1 mm in length and small spherical granules. The residual grafts material was divided into three categories (A, B, and C):

- A. Mainly CS
- B. A heterogeneous mixture of CS and calcium phosphate
- C. Mainly calcium phosphate.

The areas which appeared dense and surrounded consisted of Category C material which means that calcium phosphate represented the final stages of the resorption process. This study revealed that complete resorption of CS did not occur 4 months after the sinus lift procedure, additionally, CS resorption in the maxillary sinus was accompanied by calcium phosphate precipitation which may contribute to its biocompatibility and rapid replacement by bone.^[20]

In 2012, Dasmah *et al.* conducted a case series to evaluate CS as bone graft substitute in sinus floor augmentation clinically and histologically. In their study, 10 patients received maxillary sinus elevation using CS as a grafting material and the grafted site was covered with resorbable membrane. After 4 months of sinus lift procedure, 40 dental implants were placed and bone biopsies for histomorphometric analysis were harvested. Radiographs were taken at the time of sinus augmentation and after 4 months of graft healing. The findings of this study revealed that the survival rate of the implant was 97.5% after 1 year of loading as one implant was lost at the time of abutment surgery.

Radiographs showed a mean shrinkage of 26.5% of the augmented area. Histological evaluation revealed that a significant resorption of CS was detected with a mean value of 8.8% of remaining graft material. After 4 months of the procedure, analysis also revealed new bone formation with a mean value of 21.2% of the total biopsy area. The results of this study are consistent with the previous case series conducted by Slater *et al.* where residuals of CS were detected in the graft site 4 months after the maxillary sinus lift procedure.^[11]

In 2013, AlGhamdi *et al.* conducted a longitudinal case series study to evaluate the success of composite grafts – bovine bone and CS as grafting material in osteotome maxillary sinus lift procedure done on 18 patients. Patients were followed for an average of 23.4 months post-implant loading. A mixture of bovine bone and CS was used on 31 internal sinuses lift procedures that were performed. The ratio of this mixture was 4:1. Implants were loaded 4–5 months post-implant surgery. The findings of this study revealed that 4–5 months after implant placement, the radiograph showed a 1.5–5 mm apical shift of the sinus floor which was maintained to the end of the evaluation period. At 12 months post-loading, crestal bone loss ranged from 0.5 to 1.5 mm (mean, 0.87 ± 0.26 mm), and pocket depth varied from 2 to 4 mm (mean, 2.9 ± 0.67 mm). The authors of this study concluded that when a mixture of bovine bone and CS was used as a sinus augmentation material along with internal sinus lift procedure, the addition of CS significantly improved the handling properties of bovine bone and helped to stabilize the bone graft particles during healing period.^[21]

In 2015, Laino *et al.* assessed and evaluated a radiographic gain after external maxillary sinus floor lift procedure using CS as grafting material in 25 patients. The graft site was covered by collagen membrane. Cone-beam computed tomography (CBCT) analysis was done before and about 6 months after sinus lift procedure. The radiographic results showed that the mean vertical residual bone before surgery was 4.04 ± 1.48 mm while the mean of regenerated sites was 12.25 ± 3.20 mm at 6-month post-operative, so the mean of bone gain was 8.21 ± 1.73 mm. The authors concluded that CS showed promising results and there was bone gain higher in sites incorporated using CS as opposed to the level of bone before surgery.^[22]

Clinical Trial

In 1999, De Leonardis *et al.* conducted a clinical and histological study to compare two different

techniques for CS application in external maxillary sinus lift procedure. The study consisted of two groups: A control group: 12 patients (15 sinuses) in which the material was carefully placed but not stratified and no membrane was used to cover the graft site and, the test group: 45 patients (50 sinuses) were treated by careful stratification and compaction of CS within the sinus and around the implant and CS was applied only when it had a putty consistency. Moreover, a fast setting solution was used to speed the setting time of the material and to achieve the hardest consistency possible. In the test group, a resorbable barrier was placed to cover graft material before flap suturing. The histologic samples were collected, either at 9 months, at the uncovering procedure (for implants placed simultaneously with grafting material), or at 6 months at the time of implant insertion (for implants placed at a later stage) for analysis. The finding of this study revealed that the augmentation procedure resulted in new bone formation within the sinuses when they were clinically and radiographically evaluated. The graft shrinkage was 6 mm (2 mm–10 mm) in the control group while in the test group, it was 2.5 mm (1 mm–4 mm). On histologic analysis, new bone formation with progressive lamellar maturation was found in both the groups. Some particles produced by CS resorption were still present after 6 months in the test group specimens, but no longer detectable after 9 months. A mean histomorphometric bone density of the control group was $34.25\% \pm 10.02$ versus $55.54\% \pm 19.82$ in the test group. The authors of this study concluded that results of this study showed the importance of CS application technique in reducing the graft shrinkage during healing, which is essential to reduce the resorption rate, giving a chance for new bone formation.^[23]

In a study conducted in the year 2006, Scarano *et al.* compared nine different materials used in maxillary sinus lift procedure on 94 patients using radiographic and histologic analysis. Each patient underwent one biopsy after 6 months of the sinus lift surgery. Results manifested that none of the 94 patients had any complications, all the implants were stable, and radiographic examination showed dense bone around the implants. Histologically, in terms of new bone formation and comparing to autologous bone, DFDBA, two types of xenograft (Bio-Oss and PepGen P-15) and four types of synthetic grafts (Biocoral, Bioglass, a synthetic

copolymer polylactic and polyglycolic acid graft, and hydroxyapatite), CS was found to be the fourth best materials. The graft that resulted in greater percentage of new bone formation was autograft (40.1 ± 3.2) followed by Bio-Oss and Biocoral (39%) then by CS (38 ± 3.2), while in term of percentage of residual graft material, the less residual graft material was found to be the synthetic copolymer polylactic and polyglycolic acid graft (3 ± 2.1) followed by CS (13 ± 2.1). This study revealed that CS is one of the best biomaterials for sinus elevation augmentation due to its ability to improve new bone formation and its great restorability as compared to other graft materials 6 months after sinus lift surgery.^[24]

In 2016, Gultekin *et al.* conducted a clinical trial to evaluate the percentage of graft volume reduction following external sinus floor lift with either slow resorbable bone graft (deproteinized bovine bone [DBB]) in 18 patients and a composite of slow and fast resorbable bone graft (DBB and CS) in 17 patients using CBCT analysis. CBCT was taken before the procedure, within 2 weeks of the surgery, and 6 months after sinus lift procedure. The results showed that a significant graft volume reduction was observed between 2 weeks and 6 months after sinus lift in both the groups; however, the DBB group exhibited significantly less volume reduction than the composite group. The authors concluded that these bone substitutes can be successfully used alone or as a composite in external sinus lift procedures.^[12]

In 2016, Ahmet *et al.* conducted a clinical trial to compare two composite bone graft materials (CS + DBB vs. CS + alloplast (60% synthetic HA and 40% β -TCP)) for external maxillary sinus lift procedures in 16 patients histologically, histomorphometrically, and radiographically. Bone biopsies were harvested 5 months after the sinus lift procedure at the time of implant placement. The finding of this study revealed that the mean percentages of new bone were $34.40\% \pm 18.91\%$ for the CS + alloplast group while for the CA and CS+DBB group, it was $36.71\% \pm 15.32\%$. The percentages of residual graft particles were $6.98\% \pm 5.09\%$ for the CS + alloplast group and $5.52\% \pm 4.12\%$ for the CS + DBB group. The overall loss of the graft height was 4.14 ± 0.58 mm for the CS + alloplast group and 2.52 ± 0.67 mm for CS+DBB group. The authors in their study concluded that that both graft composites were biocompatible and effective for maxillary sinus augmentation,

however, CS and alloplastic mixture showed greater bone height loss during healing than CS and bovine bone graft mixture.^[25]

DISCUSSION

In the present review study, after searching the database on PUBMED, MEDLINE, or Google Scholar, only the articles that reported the use of CS alone or as a composite bone graft in maxillary sinus lift procedures were included, rest were excluded from the present study. This includes all the 16 published studies including one animal study, three case reports, eight case series, and four clinical trials. It is a well-documented fact that CS has been in use for decades for orthopedics, plastic surgery, and oncologic and maxillofacial surgeries for the treatment of osseous deficiencies.^[26] Animal and human clinical trial studies showed the safety and biocompatibility of CS since no adverse reaction or bone healing interference was noted.^[10,17] In addition, CS stimulates neovascularization/angiogenesis and improves new bone formation when it is used as a grating material.^[10]

In a study done by Dasmah *et al.* in 2011, on rabbit maxilla model, CS exhibited fast resorption at 2 weeks with no residual CS detected at 4 weeks or 8 weeks of treating bone defects with CS, which was in contrast with the study done by Scarano *et al.* (2006) and De Leonardis *et al.* where they reported that the complete resorption of CS after maxillary sinus procedure in human histological studies does not occur before 4–6 months.^[24,27] However, two similar case series reported complete resorption of CS 6 months after sinus lift augmentation procedure was carried out.^[18,19] Study conducted by De Leonardis *et al.* noticed the importance of CS application technique in maxillary sinus in reducing the graft material shrinkage which will ultimately slow down the resorption rate.^[23] They suggested the following technique for applying CS in maxillary sinus:

- CS is applied only when it has a putty consistency
- Special attention is given to the careful material stratification; the first layer should be compacted with a dry gauze against the bony walls for approximately 1 min to achieve good hemostasis while the subsequent layers of material should be packed and allowed to harden in an environment that was as dry as possible
- Fast setting solution should be used to speed the material setting time and to achieve the hardest consistency possible

- Before flap suturing a resorbable barrier should be placed on the outer surface of the graft material, on the lateral window
- Whenever simultaneous implant placement is not possible because of limited residual crestal bone, poles made of preset CS should be used to keep the sinus membrane elevated. The poles are created by modeling the CS to make cylindrical struts that are approximately 5 mm in diameter and 13 mm in height. The material is then allowed to set completely (for at least 15 min) before placement in the patient's mouth. As and when needed, the poles are trimmed to the desired size and shape for accommodation within the sinus.

The conventional technique recommended by De Leonardis *et al.* emphasizes the use of resorbable membrane to cover CS graft after external maxillary sinus procedure however, Pecora *et al.* (1997) found that CS can be used as a barrier and was able to exclude epithelium and connective tissues, allowing bone regeneration during healing in Sprague-Dawley rats.^[23,28] However, further studies are required to be conducted to evaluate the need of a resorbable membrane after grafting maxillary sinus with CS.

In both the maxillary sinus elevation techniques either internal (indirect/crestal approach) or external (direct/lateral window approach), CS can be used successfully as a grafting material either used alone or in combination of another graft material.^[12,16,21] Studies have reported that histologic and radiographic evaluation showed the capability of CS to improve new bone formation in sinus lift augmentation procedures.^[22,27] Scarano *et al.* (2006) reported in his study that when compared to the gold standard autograft and other bone substitutes which were used, residue of CS found 6 months after sinus lift augmentation was less as compared to the autograft and other six bone substitute materials, while the amount of new bone formation produced was close to that produced when autograft was used.^[24]

CONCLUSION

In the present review, it can be concluded that CS is a cost-effective option since the reviewed studies showed its effectiveness and biocompatibility as a grafting material for maxillary sinus lift procedure and the fast resorbing and graft shrinkage issue can be managed by a careful application of CS in layers.

Since in this present study, only one randomized clinical trial (RCT) was found comparing CS alone as a grafting material in maxillary sinus lift procedures when compared to other bone substitutes, thus more RCTs are required to be carried out in this aspect for further evaluation and to eliminate any confounding factors if present.

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