

# Correction of Alveolar Cleft With Calcium-Based Bone Substitutes

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**Abstract:** The criterion standard of alveolar cleft repair is iliac crest bone graft before secondary canine eruption. Tooth eruption has never been shown to occur in synthetic bone substitute, and there is no ideal autologous bone graft for primary repair. This prospective study evaluated alveolar cleft grafting with a calcium substitute before primary canine eruption.

Ten consecutive patients with complete cleft lip, palate, and unilateral alveolar cleft with reasonably aligned arches were grafted beginning in January 2003 to March 2007. Mean age at surgery was 10.4 months. Follow-up ranged from 3 to 7 years. Radiologic evaluation of alveolar ridge was performed at the age of 4.

All 10 patients were operated on by the same surgeon using the same technique, that is, conservative elevation of nasal, oral, and anterior alveolar mucosal flaps around the cleft, closure of nasal and oral flaps, placement of 1 to 3 mL of calcium substitute paste or crystals in the pocket, and closure of the anterior alveolar mucosa. All 10 patients healed without complication. Clinical evaluation revealed a well-healed arch with primary canine growth in the area of the previous cleft. Adequate normal bone formation and often a descending secondary canine were radiologically confirmed.

Calcium substitutes offer significant advantages over other biomaterials as well as autologous bone grafts particularly in the primary alveolar cleft reconstruction. Our study has shown for the first time that teeth can erupt through this material, which turns into a normal functioning bone in the alveolar ridge.

**Key Words:** Alveolar cleft, calcium bone substitute, tooth eruption, synthetic bone graft

(*J Craniofac Surg* 2011;22: 854–857)

**B**one grafting the alveolar cleft is the essence of managing this defect. Its benefits have been adequately previously described and include “stabilization of the maxillary arch, elimination of oronasal fistulae, creation of bony support for subsequent tooth eruption, and reconstruction of the hypoplastic pyriform aperture and soft tissue nasal base support.”<sup>1</sup>

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Received March 30, 2010.

Accepted for publication October 11, 2010.

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The authors report no conflicts of interest.

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ISSN: 1049-2275

DOI: 10.1097/SCS.0b013e31820f7f19

Although the criterion standard remains secondary repair, just before eruption of the secondary canine, with iliac crest bone graft, there is still great controversy regarding the timing of surgery.<sup>2</sup> Significant benefits are derived from grafting before primary canine eruption in early childhood. Prevention of transverse maxillary collapse and distortion between the upper and lower arches may reduce orthodontic treatment time as well as the need for orthognathic surgery.<sup>3</sup> Early obliteration of the alveolar oronasal fistula with its concomitant liquid escape, oral hygiene, and emotional issues in this childhood period are additional benefits.<sup>2</sup> The use of more conservative techniques that avoid dissection of important growth centers has overcome concerns over possible midfacial growth impairment.<sup>1</sup> In addition, good results have also been described with onlay rib and calvarial grafts.<sup>3–6</sup>

In this study, what we have shown is that there is no need for any autologous bone graft by showing that teeth can erupt through what appears to be normal alveolar bone growth stimulated by the placement of calcium bone substitute (calcium sulfate) in the alveolar cleft. To our knowledge, no such finding has been previously published. This study was based on an original idea of the first author. Parents were fully informed on the pros and cons of the various methods as well as the current management of alveolar clefts, the timing, and the original and unproven nature of calcium substitute grafting. There was no financial interest or compensation for anyone of the authors.

In the 10 consecutive patients that we present, there were no patients whose families opted out of this decision in favor of more traditional methods. The overwhelming reasons given by our patient population were the fears of the emotional and psychologic effect of the gaping alveolar cleft to the child as well as to the parents for the seemingly long waiting period until the time for secondary bone grafting. Moreover, avoidance of a donor deformity was also of paramount importance.

## MATERIALS AND METHODS

A simple protocol was set up in this prospective study, which took into consideration the financial constraints of our patient population as well as ethical issues. The children were operated on between January 2003 and March 2007. They were consecutive and with full consent of the parents. All 10 children had complete cleft lip and palates with unilateral alveolar clefts (Fig. 1). There were 7 boys and 3 girls. There was 1 bilateral cleft lip but with unilateral alveolar cleft. Six clefts were left sided and 4 were right sided. Arches were reasonably well aligned. No other exclusion criteria were used. Furthermore, aside from the clinical outcome, a panorex and an occlusal radiograph were obtained approximately at the age of 4 years when the child could cooperate to evaluate the alveolar bone growth and the existing unerupted teeth.

A synthetic bioabsorbable bone graft material based on calcium sulfate, Stimulan (Biocomposites, Staffordshire, UK), was applied to all of our patients. All patients were operated on by the first author (S.A.L.). Calcium sulfate powder diluted enough to form an injectable paste and calcium sulfate pellets were used alone or in combination

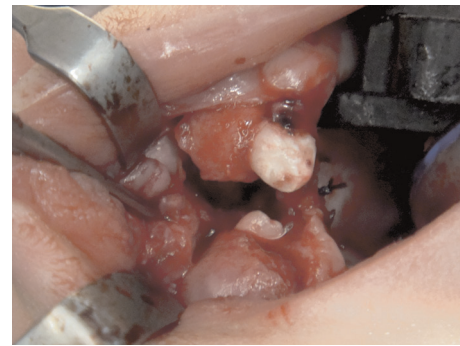


**FIGURE 1.** Preoperative image of right alveolar cleft.

(Table 1). Once the consistency of the paste was appropriate, the material was placed in the bed of the alveolar cleft pocket and allowed to dry. The bone substitute material could also be injected. On the other hand, calcium sulfate pellets can be used directly without waiting to dry out. Before placement of the material, nasal and oral mucosae are sutured (Fig. 2). The anterior alveolar mucosa closed after the graft has been placed and dried (Figs. 3 and 4). The technique involves conservative elevation of the nasal and oral mucosa enough to create an adequate pocket approximating the desired size of the alveolar ridge in that area. Intravenous antibiotics consisting of a broad-spectrum cephalosporin was given for 24 hours. The patient went home the next day on per os antibiotic therapy for 4 more days.

**RESULTS**

Surgery was uncomplicated in all 10 patients. Mean age at surgery was 10.4 months. Follow-up ranged from 3 to 7 years. Mean follow-up was 5.1 years. All patients maintain good contour and



**FIGURE 2.** Clinical view of the surgical site: bone defect with closure of nasal and oral mucosa.

without clinical evidence of significant resorption of the implant turned bone. No infection or any other complication related to the material was observed. Moreover, there was a stable maxilla, reasonable arch formation, and excellent tooth eruption. The postoperative radiologic evaluation revealed adequate bone formation with descending secondary canine visible in the older patients. Although the patients will certainly need orthodontic treatment, none of the patients required a second operation. Deciduous tooth eruption in the cleft area was indeed delayed as has been previously noted in clefts by others.<sup>7,8</sup>

**DISCUSSION**

The primary reason for the use of autologous bone grafting has been the concern that no bone substitute has the dynamics necessary for later tooth eruption. An ideal material for alveolar cleft defects, therefore, must closely approximate the normal physiology of bone formation. A biosynthetic material that best supports both structure and function of bone restoration will exhibit the following properties: biocompatibility, stability (lifetime duration), mechanical strength, capability of ingrowth, pliability (moldable to implant site), compatibility with imaging studies, and resistance to infection. Calcium sulfate presents many of these properties and could become a widely used bone substitute in alveolar arch defects.

An inorganic osteoconductive substance such as calcium sulfate acts primarily as a space filler, which restores morphologic contour, prevents the ingrowth of soft tissue, and provides an osteoconductive matrix for the ingrowth of blood vessels.<sup>9-11</sup> Histologically, new bone is remodeled from calcium sulfate and becomes contiguous with the

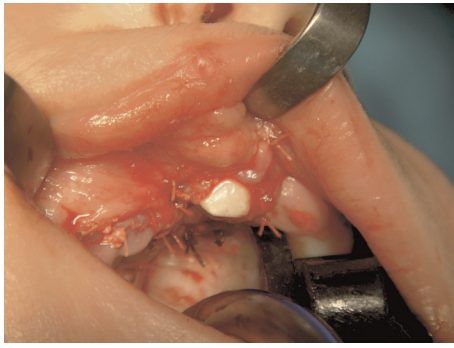
**TABLE 1.** Results of Alveolar Cleft Correction With Calcium Sulfate in 10 Patients

Patient	Age, mo/Sex	Type of Defect	Type of Material	FU, y	Tooth Eruption
1	12/M	UAC, CP, CL	Pellets	7	Present
2	11/M	UAC, CP, CL	Injectable paste	7	Present
3	11/M	UAC, CP, CL	Injectable paste/pellets	5	Present
4	11/M	UAC, CP, CL	Pellets	5	Present
5	10/M	UAC, CP, CL	Pellets	5	Present
6	10/F	UAC, CP, CL	Injectable paste	5	Present
7	10/M	UAC, CP, CL	Pellets	5	Present
8	10/F	UAC, CP, CL	Injectable paste/pellets	4	Present
9	9/F	UAC, CP, CL	Injectable paste	4	Present
10	10/M	UAC, CP, CL	Pellets	4	Present

CL indicates cleft lip; CP, cleft palate; FU, follow-up; UAC, unilateral alveolar cleft.



**FIGURE 3.** Intraoperative photograph: maximal placement of calcium sulfate pellets in the alveolar cleft.



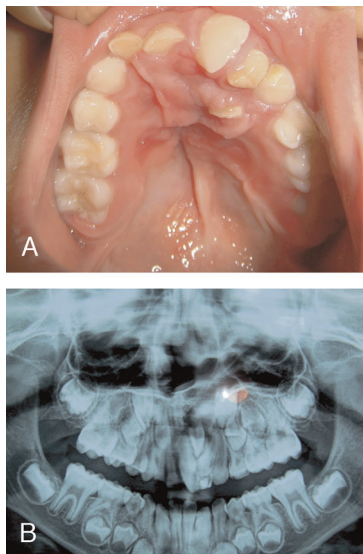
**FIGURE 4.** Closure of the flaps with absorbable suture.

adjacent native bone, being indistinguishable from the autogenous bone filling the grafted sites in a period of 24 weeks.<sup>10,12,13</sup>

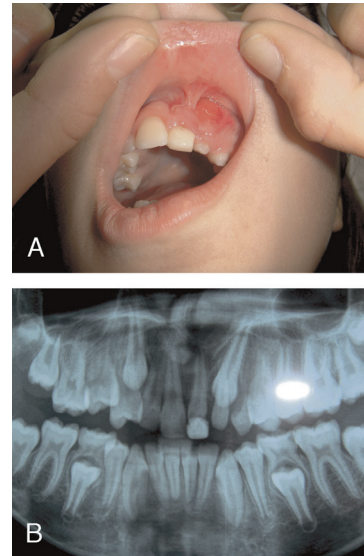
Several recent animal studies showed safe and reliable alveolar bone regeneration using recombinant human bone morphogenetic protein.<sup>14,15</sup> Although it was not applied in our study, it may be worth considering, particularly in older children.

The great moldability that calcium sulfate presents is equal to or better than that of cancellous bone. It can also be prepared thin enough to be injected in case of resorption, although in our patients, there was no need to do this. In addition, during our study, none of our patients showed any evidence of foreign body reaction to the implant material or infection at the implant site. This was assessed by physical examination and was indicated with imaging studies (Figs. 5A–7B). Finally, in our experience with this material, we have not encountered any case of microfragmentation. Whatever resorption may have occurred was not clinically significant.

Last but not least, the authors are not aware of a previous study presenting that (1) tooth eruption can occur through a synthetic bone graft in alveolar clefts and (2) before deciduous tooth eruption. Given this, the use of calcium-based bone substitute has significant advantages over other biomaterials and autologous tissue in



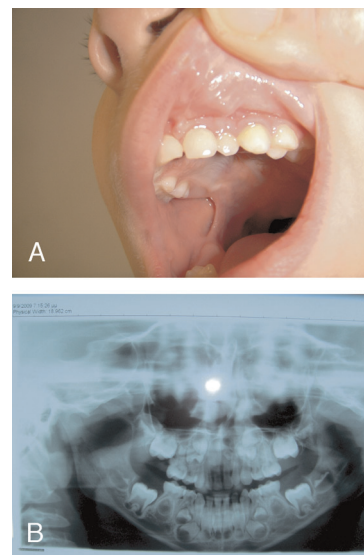
**FIGURE 5.** A, Seven years after bone substitute application, it is possible to observe the normal teeth eruption. B, Postoperative dental x-ray 7 years after calcium sulfate application.



**FIGURE 6.** A, Patient 5 years after surgery. B, X-ray 5 years after surgery.

the correction of alveolar clefts. Obviously, taking the material off the shelf is a great advantage as it obviates the need for a donor site, reduces anesthesia time, reduces morbidity, and decreases the expenses because 5 mL of the material costs approximately US \$680 and 10 mL costs approximately US \$800. Biocompatibility and resistance to infection seem to be additional benefits.

In conclusion, the application of calcium-based bone substitute in patients with congenital alveolar clefts seems to be very promising. The authors also hypothesize that this kind of material facilitates the primary alveolar cleft repair in relation to the secondary grafting. The small number of patients and the short period of follow-up of our study indicate that more studies are required. Success with calcium bone substitutes in secondary alveolar cleft grafting also remains to be seen.



**FIGURE 7.** A, Patient 7 years after surgery. B, X-ray 7 years after surgery.

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