Calcium Phosphate Cements to Control Bleeding in Osteoporotic Sternums

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Purpose. A new method to control bleeding from fragile, severely osteoporotic sternums in patients undergoing open heart surgery.

Description. From January 2006 and January 2007, we used orthopedic calcium phosphate cement in 11 patients to control sternal table bleeding. Each patient had greater than 35% of their sternal table surface missing and had associated bleeding after open heart surgery. The cement was packed into the deficient sternal table surface at the conclusion of surgery, just prior to closure.

Evaluation. All patients had immediate cessation of bleeding from their sternums, despite large superficial sternal deficits, after the cement was applied. All patients made uneventful recoveries and none required exploration for bleeding after surgery. There were no instances of superficial or deep sternal wound infections. At follow-up all sternums were well healed and firm. Seven patients had computed tomographic scans performed at 6 months revealing excellent complete sternal healing.

Conclusions. Calcium phosphate cement can be used safely to control bleeding in patients with osteoporotic sternums and seems to be safe to use in the sternum.


Technology

A median sternotomy is a common approach to the heart during cardiac surgery. Bleeding from the bone marrow matrix can be a significant problem, especially in elderly patients with significant loss of their sternal table surface due to osteoporosis [1]. These fragile sternums lack a bony matrix facade preventing platelet surface contact and clotting. Several agents are used to tamponade sternal table bleeding [1–6]. They are all unfortunately foreign bodies, except Vivostat (Vivolusion, Birkeroed, Denmark) [3]. Those that do not biodegrade can initiate infection at a later date. Moreover, none become incorporated by the body into bone. In patients with large areas of sternal bone loss, robust amounts of bone wax have typically been used to control bleeding [7]. Unfortunately this practice is associated with a higher incidence of sternal infections and sternal dehiscence [7]. We report the use of calcium phosphate cement as an alternative to bone wax and other agents used to control sternal bleeding in osteoporotic patients.

Clinical Experience

The calcium phosphate material used in our study, Callos (Skeletal Kinetics, Cupertino, CA) is composed of soluble salts, which when combined with a sodium silicate solution begins a reaction that results in the formation of a hydroxyapatite agent and the material constituent of bone [8, 9]. This reaction occurs continuously from the start of the mix until the material fully cures in vivo patients in this group had bleeding from severely osteoporotic sternums. Each had deficient bone marrow, such that their sternal tables were missing greater than 35% of the sternal surface and had a defect that was at least 1 m deep. These 11 patients make up our study and were treated with an orthopedic cement to control bleeding. Sternal table defects were visually estimated. Only patients with extremely friable osteoporotic sternums received the study product. The sternal tables of the patients were treated with calcium phosphate salt bone filler in an effort to obtain hemostasis. Typically 5 to 10 cc of bone filler was used per patient. No other topical agents were used. Standard cardiopulmonary bypass techniques were used. The sternum was closed with eight sternal wires placed before the cement. No other methods were used to stabilize the sternum at closure. The Ethics Committee approved this study and waved any surgical consent as patients were not identified during the study.
during the 24 hours after implantation. The initial setting of the material corresponds to chemical precipitation of small crystals of hydroxyapatite so that the continuation of this reaction results in the hardened, fully cured material. Analogous to the curing and setting of concrete, the calcium phosphate cement is a hydraulic cement that must be kept warm and wet to ensure proper setting and curing. The fully cured hydroxyapatite material is stable in vivo and will not dissolve with physiological blood pH (pH = 7.4). However, it will be remodeled along with native bone in a stress-dependent fashion so that areas of high bone turnover (ie, areas of high loading) will be sites of higher calcium phosphate cement turnover. This substance is Food and Drug Administration approved for use in orthopedic surgery as a bone filler in crush fractures [8–10]. It has the advantage of adding structural strength to collapse weight-bearing fractures (ie, calcaneal fractures, tibial plateau fractures) and is strong enough to accept screws and pins immediately after setting [8–10]. However, it has not been known to be hemostatic.

This solution was mixed until it reached a paste consistency. It was then inserted between the sternal tables, after the sternal closure wires had been placed. The solution was actively paced to appose and tamponade the remaining sternal table. Most likely the cement provided a surface for the clotting cascade and subsequent hemostasis. It controlled bleeding immediately by tamponading bleeding from the remaining sternal table. Most likely the cement provided a surface for platelets to adhere to and initiate a platelet plug, commencing the clotting cascade and subsequent hemostasis. Calcium phosphate cements are advantageous in treating patients with sternal table loss, which can be very difficult to get to stop bleeding. Bone wax has been widely used for this purpose [1–7]. Unfortunately the use of excessive amounts of bone wax, as would have been required in our patient population, is very difficult to get to stop bleeding. Bone wax has classically been used for this purpose. [1–7]. None of our patients suffered any of these complications. All patients experienced excellent sternal and soft tissue healing. At follow-up, using chest computed tomography in a select group of patients followed up for a short period of time, we found evidence of excellent sternal healing and complete replacement of the sternal deficits by bone. This is consistent with the findings described in the orthopedic literature when...
calcium phosphate cements are used in weight bearing fractures [10]. The long-term prognosis of our patient’s sternal tables is not known. However, soluble calcium phosphate salts are known to remodel as bone in other parts of the body without long-term complications. We anticipate a similar fate in the sternums of our patients. Our short-term findings support this.

Calcium phosphate material, unlike bone wax, is made up of soluble salts naturally found in the body [8]. The material is Food and Drug Administration approved and has been used in orthopedics as a bone filler to allow early weight bearing in fractures that traditionally have not permitted weight bearing for a long period of time [10]. Bony healing after use of this cement occurs through a process called osteoconduction. Osteoconduction lays down the architecture or scaffolding for osteoclasts to populate and form to bone. This process occurs while providing support for weight bearing and a surface for blood to clot against. It can be used very easily and safely in large amounts. Allergic reactions have not been recorded and are unlikely as the salts used are naturally found in all bone.

The Callos cement (Skeletal Kinetics) used in our study has an advantage over other calcium phosphate cements on the market. Unlike other Food and Drug Administration approved cements, it is the only one approved to accept pins and screws to fixate other bones or plates into it directly, as it does not fracture or crack when drilled into. This may be important in accepting sternal wires used during the closure of the sternotomy or in complex sternal rewiring. As with other cements, it is biocompatible, easy to mix and deliver, and adds very little time to the operative procedure. Typically mixing and application add less than 5 minutes to the procedure. It sets quickly in a warm and wet environment, such as bleeding associated with open heart surgery, and no washout occurs.

The limitations of our study are the small patient study size, limited follow-up, and lack of a comparison cohort. Larger number of patients followed for a longer period of time compared with a control group using bone wax or other hemostatic agents will be needed to determine if the cost of the calcium cement ($900 per 5 cc) can be justified, and if its use is associated with a lower incidence of sternal wound infections and dehiscence. However, we can suggest Callos (Skeletal Kinetics) as an alternative to other foreign bodies, especially bone wax, to control bleeding in patients with osteoporotic frail sternums. We are uncertain as to its importance in sternal strength after sternotomy incisions. Our study population was too small to suggest an advantage to sternal healing, strength, and decreasing infection. We anticipate the cement will likely provide better bony healing, and therefore decrease the incidence of dehis-cence and infection. However, exactly how important stress related remodeling is to sternal replacement of calcium cements is not know. Our preliminary follow-up chest computed tomographic scans suggest that bony replacement occurs quickly. Whether bone marrow stem cell will populate this area and allow blood formation to occur is unknown. It is unlikely that these bone filler cements will be able to replace large areas of sternal loss due to infection as the sternal tables are necessary to contain the material while it cures.

Disclosures and Freedom of Investigation

No funds were relieved to perform the study. All products were purchased by the hospital and the authors had full control of the design of the study, methods used, outcome measurements, analysis of data, and production of the written report.

References


Disclaimer

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