

Contouring of Cranial Vault Irregularities With Hydroxyapatite Cement: A Clinical and Experimental Investigation

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Abstract: The biocompatible hydroxyapatite cement (HAC) is a welcome alternative to the traditional use of autogenous bone for postoperative corrections of cranial vault irregularities. The authors performed experimental studies to show the safety and osseointegration capacity of HAC on animal models and confirm the osseous replacement without toxic reactions. The purpose of the current study was to analyze the clinical outcome after correction of secondary cranial vault irregularities with HAC. Twenty-one patients were treated for residual cranial frontal bone defects after craniotomy with HAC (Bone Source®, Stryker Leibinger GmbH, D-79111 Freiburg, Germany). The average age was 38.5 years (range, 23–57 years). All of the patients were male. The average volume per patient was 53.83 g. The volume implanted ranged from 25 to 125 g; in all cases the dura was covered with bone. Irregularities resulted from sunken bone. The authors' clinical series demonstrates that a satisfactory and aesthetically pleasing result can be achieved in one surgical intervention in patients for surgical correction of postoperative cranial vault irregularities using HAC. It permits osseointegration, which makes it relatively resistant to infection. HAC is easy to apply and shape to suit individual needs. HAC is a welcome alternative to the traditional use of autogenous bone for postoperative corrections of cranial vault irregularities.

Key Words: Bone source, cranial vault, hydroxyapatite cement (HAC)

Secondary craniofacial contouring is a commonly performed procedure for postoperative cranial vault irregularities. Several materials have been used for this procedure.¹ But shortcomings of autogenous materials have increased the popularity of alloplastic materials, such as hydroxyapatite cement (HAC). This material is an alloplastic material composed of tetracalcium phosphate and dicalcium phosphate

anhydrous that transforms into a paste-like substance when these compounds are placed in a liquid environment.^{2–8} It has a high osteoconductive capacity, so HAC is an excellent alternative for craniofacial refining.⁹

The purpose of this study was to analyze the clinical outcome after correction of secondary cranial vault irregularities with HAC.

PATIENTS AND METHODS

Patients

The patients treated were those undergoing elective cranioplasty for reconstruction of frontally orientated cranial vault irregularities after craniotomy (Fig 1). Twenty-one patients who underwent frontal cranial vault plasty were implanted with HAC (Bone Source®, Stryker Leibinger GmbH, D-79111 Freiburg, Germany) during a 48-month period. The average age was 38.5 years (range, 23–57 years). All of the patients were male. Patients were treated for residual cranial frontal bone defects after craniotomy. The average volume per patient was 53.83 g. The volume implanted ranged from 25 to 125 g; in all cases the dura was covered with bone. Irregularities resulted from sunken bone.

Technique

We knew from our animal investigation that the intraoperative time is dependent on solubility of the powders, which primarily is regulated by the liquid solvent, and that the liquid solvent used influences the osseointegration by decreasing the microporous structures and porosity rate. With a mean diameter between 5 and 10 nm, water was used as a solvent in our study. It has a set time from 30 minutes and enables the surgeon to mold and reshape the HAC over the corrected cranial vault irregularities and enables a homogenous osteoconversion over a shorter time.

Using a coronal approach and reflecting the frontal orbital flap to expose the cranial vault, HAC was used in infection-free, good quality surrounding and underlying bone beds with adequate, well-vascularized overlying tissue. No full-thickness cranial defects were corrected with HAC because these defects require a floor to contain the HAC while setting and to dampen dural pulsation. After the powder and liquid compositions were mixed intraoperatively, the paste was contoured into the cranial vault defect and subsequently converted in vivo by direct crystallization without heat formation to hydroxyapatite. Once applied, the putty was molded into the

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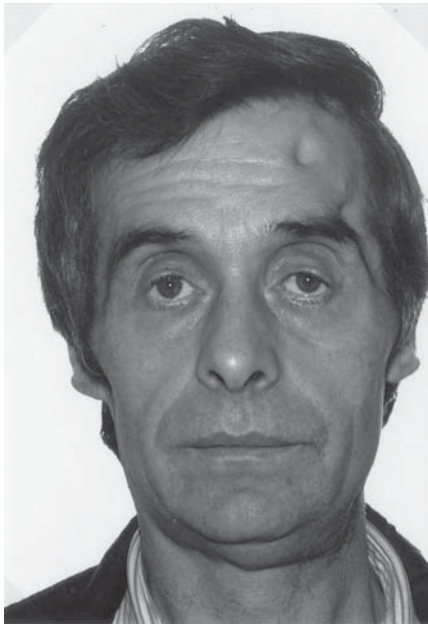


Fig 1 Frontal view of a patient with residual cranial frontal bone defects after craniotomy of the left frontal orbital bone.

desired aesthetic reconstruction. Final contouring was followed by scraping with elevators or Tessier spatulas and molding with wet glove fingers. The solidification process was completed within 15 to 20 minutes, to form hydroxyapatite during the next 6 to 8 hours. Drainage was left in place for 24 hours.

RESULTS

The median observation time was 14 months. Immediate healing was archived without complications, adverse reactions, or side effects.

All patients healed uneventfully. No swelling or seromatous fluid collection necessitated a second procedure or prolonged drainage.

No failure of the material to set up or postoperative "wash out" of the reconstruction area was observed. Satisfactory reconstruction of the frontal cranial vault defects occurred in all implanted patients without any postoperative problems. Touch, shape, and stability were achieved 4 weeks after surgery. The following examples illustrate the indications, treatments and results (Figs 2-6).

DISCUSSION

Hydroxyapatite cement is a welcome alternative to the traditional use of autogenous bone for postoperative corrections of cranial vault irregularities.^{1,8,9}

The material maintains its intraoperative position after surgery. It is biocompatible and has good outcomes.^{1,5,8,9} Our own animal studies on histologic examination of HAC revealed fine fibrous septa containing newly formed small vessels. Sparsely distributed focal ossification areas characterized by an ossification matrix in which osteocytes in lacunae were embedded were seen. These observations support the osseointegration of the implant and showed, in the animal study, that although it was limited, there was new bone and vascularized formation within the HAC (Fig 5). The high osteoconductive capacity of HAC makes it an excellent alternative for postoperative correction of cranial vault irregularities. It is incorporated within the surrounding bony structures and permits secondary procedures. It has the potency to develop tissue in growth and integration into the

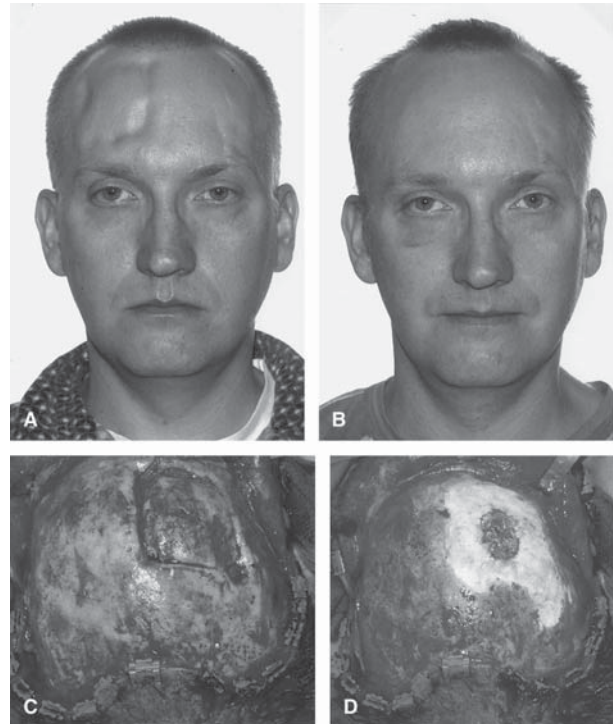


Fig 2 (A) Frontal view of a young patient with an aesthetically unpleasant residual right cranial frontal bone irregularity resulting from a sunken bone; postoperative view after cranial vault plasty with HAC. Twelve months after surgery. (B) Note the aesthetically pleasing result; intraoperative view after reflecting the fronto-orbital flap of the patient in A. (C) Note the severe sunken cranial frontal bone resulting in a depression of the frontal orbital region. (D) Intraoperative view after cranioplasty with HAC for reconstruction of the irregularity of the cranial frontal orbital vault.

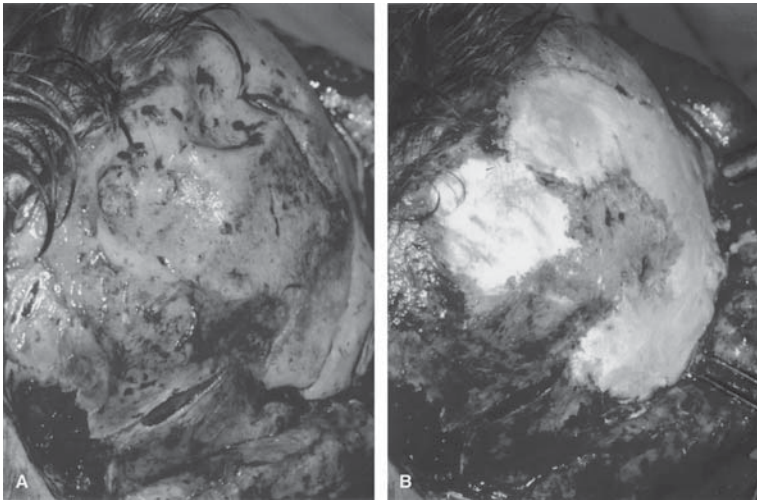


Fig 3 (A) Intraoperative view of the cranial vault deformity after reflection of the frontal orbital flap. Note the residual irregularities and deep cavities after primary craniotomy 15 months before. (B) Intraoperative view after cranioplasty of the residual craniotomy defects with HAC.

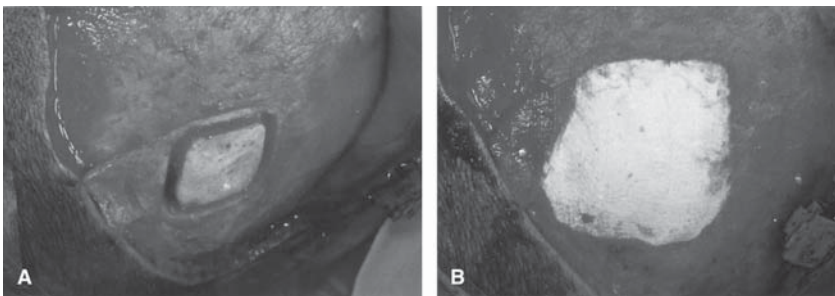


Fig 4 (A) Intraoperative view of a patient undergoing an external calvarial bone segment harvest. (B) Intraoperative view after harvesting the external table of the calvarial bone and after cranioplasty of the harvested area with HAC.

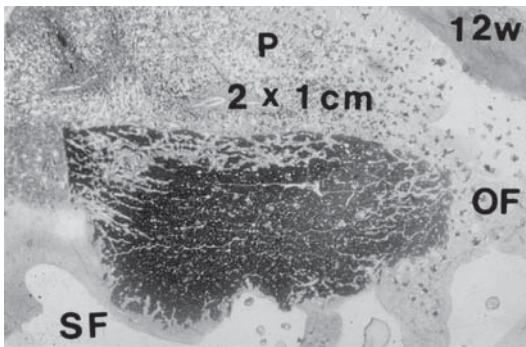


Fig 5 Microscopic view of a cranioplasty with HAC of a calvarial frontal bone of a Goettingen minipig. Twelve weeks after surgery. Sparsely distributed focal ossification areas characterized by an ossification matrix in which osteocytes in lacunae were embedded were seen. These observations support the osseointegration of the implant and showed, in the animal study, that although it was limited, there was new bone and vascularized formation within the hydroxyapatite cement. p = periosteal bone; SF = frontal sinus; OF = frontal bone. Note the bone substitution at the interface.

recipient site after placement. They do provide a physical substrate onto which new bone from adjacent surfaces may be deposited and potentially guided into areas occupied by the material.

Our own experimental studies performed to show the safety and osseointegration capacity of HAC on animal models confirm the osseous replacement without any toxic reactions or increase in serum calcium and phosphate levels as shown by Friedman et al.¹⁰ It could be demonstrated that HAC will be gradually reabsorbed and replaced by bone. The capacity for osteoinduction was found to be dependent on the rate of the porosity and microstructure, with a mean diameter of 8 nm, depending on the amount of the added solvent water, which enables the homogenous osteoconversion. But our histologic examinations on Goettingen minipigs reveal that the porosity and microstructure are dependent on the liquid substance. Mixing the HAC powder with sodium monophosphate intraoperatively decreases the microstructure of the resulting hydroxyapatite and limits the amount

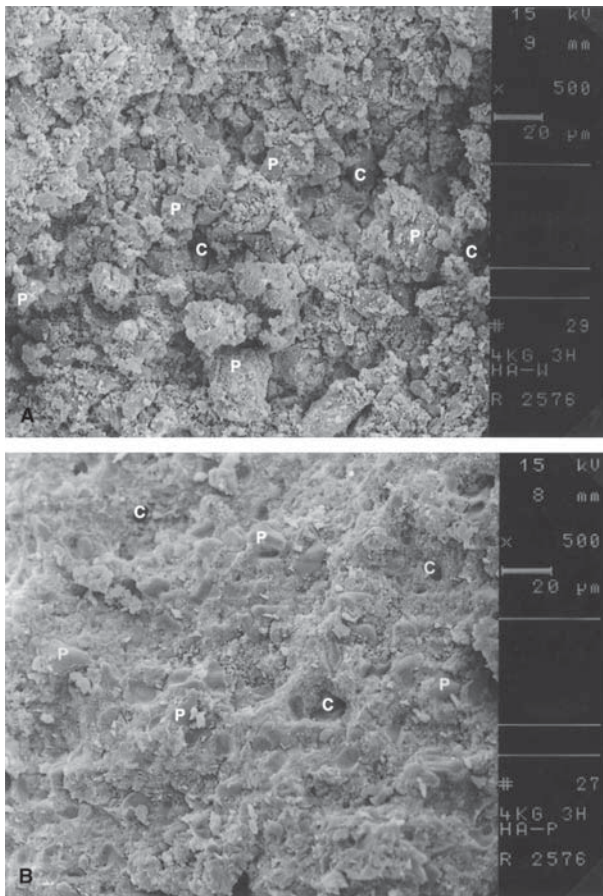


Fig 6 (A) In vitro investigation of HAC. Electronic microscopic view of a cracked HAC segment. Using aqua bidest as liquid solvent resulted in a heterogeneous crystalline matrix surface with increasing the microporous structures and porosity rate with a mean diameter between 5 and 10 nm (C). The diameter of the hydroxyapatite particle (P) ranged from 15 to 25 nm. (B) Using sodium phosphate (0.25 molar) as liquid solvent, resulting in a homogeneous crystalline matrix surface, decreasing the microporous structures and porosity rate smaller than 5 nm (C). The diameter of the hydroxyapatite particle (P) ranged from 5 to 10 nm.

of bone formation and integration into the recipient site after placement (Fig 6A, B).

Strength properties of hydroxyapatite cements vary depending on the composition of the cement powder, the grain size of the powder, and the setting conditions.^{11,12} Adding compounds also will change the compressive and tensile properties of HAC, as was shown by Fernandez et al⁷ and Ginebra et al.¹³ It also has recently been demonstrated that the biomechanical properties of hydroxyapatite cements

tend to decrease the longer the material is exposed to a moist environment.¹⁴

CONCLUSION

This clinical series demonstrated that a satisfactory result can be achieved in one surgical intervention in patients for surgical correction of postoperative cranial vault irregularities using HAC. Hydroxyapatite cement (Bone Source®) will gradually be reabsorbed and replaced by bone, if not the internal table together with the external table calvarial bone. It permits osseointegration, which makes it relatively resistant to infection. The substrate is available in amounts (volumes) that are easy to apply and shape to suit individual needs.

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