Porous block hydroxyapatite as a bone graft substitute in the correction of jaw and craniofacial deformities

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Modulation of the immune system as an approach to attack cancer has been explored for the past 50 years. Efficacy of this treatment has been achieved in a limited number of patients. However, a major obstacle of immune therapy is the toxicity related to the nonspecific nature of immune activation. Efforts to improve the specificity of the immune response have been investigated through the use of gene therapy. Clinical trials involving gene therapy for melanoma, lung cancer, and head and neck cancer have been conducted by US Oncology at the Mary Crowley Medical Research Center–Baylor University Medical Center. These studies represent one of the most active gene therapy programs in the USA. Preliminary results have helped define the mechanism of action, safety, and potential efficacy of immune stimulatory treatment approaches in oncology.

Interpositional grafting materials are often used to fill in bone gaps that result from corrective jaw surgery and craniofacial reconstruction. Various materials and autogenous bone grafts from different harvest sites have been advocated to maintain the repositioned structures. Each of these choices has inherent drawbacks. Porous block hydroxyapatite (PBHA) has provided an alternative to bone grafting in these procedures. PBHA has parallel channels of 230 ? in diameter, with interconnecting fenestrations between the channels of 190 ? in diameter. This pore size is not only similar to normal osteon size in bone (190 ?), but it also conforms to research findings of 150 to 200 ? as optimal for bone ingrowth. PBHA functions as an osteoconductive matrix when placed against or between bone structures, allowing bone and soft tissue ingrowth through it. The use of rigid fixation is necessary for stress protection of the PBHA grafts and the elimination of micromovement to enhance bone growth through the grafts. The clinical, radiographic, and histological studies of PBHA used as a bone graft substitute in corrective jaw surgery, craniofacial surgery, and facial augmentation have demonstrated the efficacy of this material for these applications, with a low incidence of complications.

Orthognathic surgery is the surgical repositioning of the jaw structures with osteotomies. Surgical correction of jaw and facial deformities may require repositioning of the upper jaw
(maxilla), lower jaw (mandible), and craniofacial structures, creating bone gaps or continuity defects. These bone gaps can be small or quite large, as seen in cases of maxillary or midfacial hypoplasia. Failure to graft these gaps can result in instability, relapse, and nonunion of the bone structures with subsequent redevelopment or worsening of the original deformity.

Various interpositional grafting materials have been advocated to maintain the repositioned bony structures. Autogenous bone grafts from the calvarium, iliac crest, or ribs as well as freeze-dried bone and the solid block form of hydroxyapatite have been used as interpositional graft materials (1–4). Each of these materials has inherent drawbacks. Autologous bone requires a secondary surgical harvest site, with its inherent morbidity, and the bone may undergo resorption and remodeling during healing, which has been associated with relapse. Freeze-dried bone undergoes significantly greater resorption and remodeling than does autologous bone, takes longer to heal, has a higher infection rate, and carries the problems of an allograft. Solid block hydroxyapatite does not allow bony ingrowth, is very difficult to shape, does not become intimately incorporated into the bony matrix, and requires autologous bone grafting to facilitate healing and stability.

Porous block hydroxyapatite (PBHA) (Interpore 200, Interpore International, Irvine, Calif) provides an alternative to bone grafting in corrective jaw surgery and craniofacial surgery. PBHA material is derived from marine coral of the genus *Porites*. This coral has an average void volume of 66%. Parallel channels are 230 μm in diameter, with interconnecting fenestrations between these channels of 190 μm in diameter (5). In 1979, Holmes (6) proposed that this coral could be processed through replamineform, converting the calcium bicarbonate exoskeleton of the marine coral into pure hydroxyapatite through an exothermic reaction (7–10). The hydroxyapatite matrix structure thus formed functions as a scaffold for bone and soft tissue ingrowth (*Figures 1 and 2*).

With autologous bone grafts, the normal healing process includes the initial revascularization and resorption of osteons. The interstitial bone remains and serves as a stromal framework for the formation of new bone. The residual bony matrix contains pores large enough to permit tissue ingrowth. Because of its special porous nature, PBHA is osteoconductive and allows intimate bony ingrowth (5). The pore size of PBHA is not only similar to normal osteon bone size (190 μm) but also conforms to research that confirms a minimum pore size of 100 μm, preferably 150 to 200 μm, for optimal bone ingrowth (6–11).

**SURGICAL CONSIDERATIONS**

The surgeon should change gloves before handling the PBHA material because oral and nasal flora and debris previously picked up on gloves during the pregrafting stages of surgery could contaminate the PBHA, resulting in a subsequent infection. Several important physical characteristics of PBHA should be noted. In its initial form, PBHA is brittle and must be handled and shaped carefully so it does not inadvertently fracture, although the material becomes very strong after healing. It is important to use irrigation when cutting the individual grafts from the larger blocks with a bur and when refining the contours with a
scalpel blade (*Figure 3*). Irrigation improves the PBHA strength, minimizes aberrant fracture, and helps keep debris out of the pores.

PBHA grafts can be used as interpositional (inlay) grafts placed between osteotomies or as facial augmentation (onlay) grafts. They can be applied to the maxilla, mandible, chin, orbit, zygoma, nose, forehead, and cranium. Onlay grafts may require stabilization by placing bone screws through the material, as in PBHA chin or cheek onlay grafts. A lag screw technique should be used with minimal tightening to prevent fracturing of the grafts.

The importance of rigid skeletal stabilization when using PBHA grafts for maxillary surgery cannot be overemphasized. Rigid fixation is paramount to provide the necessary stability and stress protection for the PBHA grafts to heal properly. The use of 4 bone plates is recommended to stabilize the maxilla (*Figure 4*), with 2 bone screws above and 2 bone screws below the level of osteotomy for each bone plate (12, 13). The grafts in the maxilla are accurately contoured and wedged in position and are not directly fixated. If there is excessive mobility between the bone segments and PBHA grafts or a functional overload, the grafts could become displaced or fractured. Alternatively, a significant decrease in the amount of bone growth through the implants could occur, resulting in a nonunion. A soft diet is encouraged for 3 to 4 months during the initial postsurgery healing phase to minimize loading and micromovement, thus preventing displacement, fracture, or nonunion of the grafts. Bone growth through the grafts is essentially complete in 4 months.

**CLINICAL AND RADIOGRAPHIC STUDIES**

Wolford et al introduced the use of PBHA as a bone graft substitute in orthognathic and craniofacial surgery (12). This research, performed at Baylor University Medical Center and Baylor College of Dentistry, resulted in Food and Drug Administration approval of PBHA for these applications. This study consisted of clinical and radiographic evaluations of 92 consecutive patients who received a total of 355 PBHA grafts, with 294 to the maxilla, 41 to the mandible, and 20 to the craniofacial region. There were 202 grafts directly exposed to the maxillary sinus. Follow-up time ranged from 8 to 24 months and demonstrated very good results. The most frequent complication occurred in 5 of 92 patients (5.4%), where a midpalatal graft used to stabilize upper jaw expansion was lost secondary to exposure of the graft to oral or nasal flora and debris, resulting from incisions or tears of the mucosa directly over the implants at the time of surgery. After identifying the causative factors, modifications in palatal and nasal soft tissue management essentially eliminated further occurrences of this complication.

Rosen and Ackerman reported on 46 patients who received PBHA grafts during orthognathic surgery, with a complication rate of 4.3% after a follow-up period of 6 to 20 months (14, 15). Moenning and Wolford reported on 49 patients, with a minimum 24-month follow-up, in whom 215 PBHA grafts had been placed during orthognathic surgery (16). Nine patients had complications, including 4 who lost midpalatal grafts, 4 who had sinusitis treated with antibiotics and decongestants without loss of grafts, and 1 patient with a partially displaced mandibular graft that remained without untoward effects.
Cottrell and Wolford clinically and radiographically evaluated 111 patients, with an average follow-up time of 7.2 years (range, 5.0 to 10.3 years). A total of 471 PBHA grafts were placed: 403 in the maxilla, 44 in the mandible, and 24 in the periorbital region (17). Twenty-three grafts (4.9%) were lost during the evaluation period. Maxillary interpositional grafting with direct exposure to the maxillary sinus had a 97% success rate, with 9 (of 289) grafts lost in 3 patients. One chin graft that was well healed was removed because of patient dissatisfaction with the aesthetics. Seven of 50 (14%) midpalatal grafts used for maxillary expansion were lost, primarily in the early cases, where soft tissue incisions or tears directly over the grafts exposed them to the oral or nasal flora and debris at the time of surgery. When PBHA was used for alveolar cleft grafting, there was a 100% failure rate (5 of 5). Therefore, PBHA should not be used for this specific application. Failure was related to the inability to achieve a watertight soft tissue closure over the PBHA graft, thus allowing leakage of oral flora into the graft.

Wardrop and Wolford published a radiographic stability study on 14 maxillary advancement cases, 11 maxillary downgraft (vertical lengthening) cases, and 3 midfacial advancement cases (13). All were stabilized with bone plates and PBHA grafts, with <0.5 mm relapse in any direction.

Castro et al recently completed a radiographic stability study of maxillary advancement of >5 mm, with rigid fixation and PBHA grafts (18). The average follow-up time for the 78 patients in the study was 25.8 months. The study demonstrated that the mean horizontal and vertical relapse was <0.5 mm in all patients, indicating good stability. Castro et al also evaluated the stability of maxillary downgrafting >5 mm using rigid fixation and PBHA grafts on 43 patients, with an average follow-up of 31.3 months (19). The results were also stable, with an average vertical relapse of <0.6 mm.

Moenning and Wolford reported a radiographic study on 12 patients in which PBHA was used for onlay grafts stabilized with bone screws to the anterior mandible for chin augmentation (20). This study showed no bone resorption, excellent stability, and radiographic evidence of bone ingrowth into the grafts.

**HISTOLOGICAL STUDIES**

Holmes et al reported on 17 biopsies of PBHA grafts used in corrective jaw surgery in 9 patients: 14 biopsies from the maxilla and 3 from the mandible (21). Histometry demonstrated an average composition of 48.5% hydroxyapatite matrix, 18% bone, and 33.5% soft tissue in PBHA grafts harvested 4.7 to 16.4 months postsurgery (Figure 5). In these biopsies, the composition of the adjacent normal maxillary and mandibular bone averaged 66.5% bone and 33.5% soft tissue, indicating that the ratio of hydroxyapatite/bone to soft tissue/vascular space is equivalent to normal bone. The study also demonstrated that bone growth through the PBHA grafts was essentially complete in 4 months, with further progression of the healing process resulting in maturation of the ingrown bone.

Nunes et al reported on the histometrics of PBHA graft biopsies from 9 patients, harvested 14 to 30 months postsurgery (mean, 19.1 months) (22). The mean composition of the
samples was 53% PBHA, 27% bone, and 21% soft tissue. The grafts had less soft tissue than the adjacent bone (30% soft tissue). The grafts had bone contact over 60% of their surfaces. A near-balance between the PBHA grafts and surrounding bone had been established.

Ayers et al evaluated 25 biopsies of maxillary PBHA grafts from 17 patients (23). The grafts had been placed into the lateral maxillary wall, juxtaposed to the maxillary sinus during orthognathic surgery, and were harvested 4 to 138 months postgrafting. Histometric examination showed the mean composition of the samples was 51% hydroxyapatite matrix, 23% bone, and 26% soft tissue. No inflammatory responses were observed. There was no significant difference in microhardness values between the bone in the PBHA grafts and the adjacent maxillary bone. Bone ingrowth appeared to plateau at around 20 months, reaching an equilibrium in which the relative amount of osseous tissue remained constant.

**DISCUSSION**

Where continuity defects exist, interpositional bone grafting is indicated in orthognathic surgery to provide bony continuity, improve healing, improve stability, decrease surgical relapse, and provide surgical stability in traditionally unfavorable jaw repositioning movements. PBHA is essentially nonresorbing and is incorporated into the adjacent bony structures, becoming a permanent part of the skeleton. The use of PBHA as an alloplastic grafting material has several advantages over other types of grafts: no donor site morbidity is involved, PBHA and adjacent bone are not resorbed, there is no known hypersensitivity or immune response, the substance is easily manipulated, there are no working time constraints, surgical time is decreased, blood loss is decreased, the volume is unlimited, and healing is faster resulting in a shorter recovery time. Prior to using rigid fixation and PBHA, maxillary downgrafting was unstable and unpredictable, resulting in significant relapse problems. The use of PBHA combined with rigid internal fixation in maxillary downgraft and advancement surgery has demonstrated long-term stability and predictability (13, 18, 19).

Biocompatibility of hydroxyapatite has been established, as well as the long-term retention of PBHA used in orthognathic and craniofacial surgery (17). Histologic studies (21–23) and a long-term clinical study (17) demonstrate good biologic acceptance of the grafts in association with the maxillary sinus.

No complications have been reported with the interdental PBHA grafts. Grafts are placed in osteotomy sites between teeth roots when the maxilla is sectioned into >=2 segments to aid in repositioning, and a bone gap is created between the segments. However, if orthodontics requires movement of tooth roots into the grafted area, PBHA grafts should not be used because PBHA will not resorb and tooth root damage is likely to occur. Autogenous interdental bone grafting should be used in this situation.

Postsurgical displacement or fragmentation of the PBHA grafts can occur as a result of the following:
1. Inadequate rigid fixation and stress protection
2. Improper contouring or placement of the implant into the osteotomy site
3. Parafunctonal habits (i.e., clenching, bruxism)
4. Poor patient compliance
5. Trauma

Infection can occur at any site but most often appears to be correlated with exposure to oral or nasal flora and debris, improper fixation, mobility of the graft, fracture of the graft and fragment displacement, or the presence of a presurgical infection in the area.

Parafunctonal habits can contribute to mobility of the maxilla, which will interfere with healing, significantly decrease bone ingrowth, and possibly cause graft fracture and/or displacement. Control of parafunctonal habits postsurgery with appropriate medications will decrease stress on the jaws and graft materials during the initial healing phase and thus will enhance outcomes.

As previously mentioned, PBHA is not recommended for alveolar cleft grafting because of a high failure rate. Cancellous iliac bone grafting works best for alveolar cleft grafting and has the advantage of allowing the eruption of the teeth and orthodontic tooth movements through the graft.

References


