

# Current Use of Bone Substitutes in Maxillofacial Surgery

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**ABSTRACT** *The use of bone substitutes in the field of facial plastic and reconstructive surgery is well established. Because of the complexity of the anatomy in the head and neck region, reconstruction and augmentation of this area pose a challenge to the surgeon. In addition, the shortcomings of autogenous bone, such as resorption and donor site morbidity, have led to the need for alloplastic implants in the field of facial plastic surgery. Multiple alloplastic implants are currently in use today; however, those compounds that contain calcium, silicon, and carbon have been examined more closely in this article. This is because of their ability to osseointegrate and osseointegrate with surrounding fibro-osseous tissue, as well as demonstrate a higher immunogenic tolerance by the human body. The discussion of each compound includes a description of its composition and structure, the advantages and shortcomings of the material, and its current uses in the field of facial plastic and reconstructive surgery. With a better understanding of the available alloplastic implants, the surgeon can make a more informed decision as to which implant would be most suitable in a particular patient.*

**KEY WORDS:** Bone; substitutes; craniomaxillofacial

Alloplastic implants have been used in the reconstruction of the craniofacial skeleton since 1600, when Fallopius implanted a gold plate to repair a cranial defect.<sup>1</sup> The advances in medicine and chemistry have created a large group of polymeric alloplasts that are being used in the reconstruction and augmentation of the craniofacial skeleton. This new medical technology has given physicians alternatives to the use of autogenous bone in the area of facial plastic and reconstructive surgery. Allografts avoid the use and subsequent morbidity of donor

sites, provide more material than may be available from the host, and reduce operative time by obviating graft harvesting. In addition, bone and cartilage may undergo varying degrees of resorption over time.<sup>2</sup> Because of the potential shortcomings of autogenous grafts, it is obvious that there is such an interest in the search for an ideal implant material. The ideal implant material should possess several characteristics: it should (1) be chemically inert; (2) incapable of producing hypersensitivity or a foreign body reaction; (3) be easily contoured; (4) re-

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**Table 1. Current Bone Graft Substitutes**

Calcium based
Calcium phosphate
Tricalcium phosphate
Ceramic hydroxyapatite
Nonceramic hydroxyapatite
Calcium sulfate
Calcium carbonate
Silicone based
Bioactive glasses
Glass ionomer cement and solids
Silicone
Miscellaneous
Polyethylene
Bone induction proteins

tain stable shape over time; (5) be easily contoured; (6) be noncarcinogenic; and (7) become ingrown or replaced by living tissue.<sup>3</sup> Thus far, the search for the alloplastic implant that meets all these criteria has not been accomplished. There are, however, some prospects within the field of facial plastic and reconstructive surgery that show promise. This article focuses on several of these bioactive bone substitutes (Table 1).

The term *bioactive* refers to materials that are capable of osseointegration and osseointegration.<sup>3</sup> Osseointegration refers to the direct chemical bonding of implant to bone without an intervening layer of fibrous tissue. Osseointegration refers to the ability of an implant to act as a scaffold on which bone can grow.<sup>4</sup> The ability of an implant material to osseointegrate imparts a greater amount of stability and fixation to the implant–bone interface. This prevents any implant movement or displacement which may lead to implant infection and to the resorption of bone under the implant.<sup>5–7</sup> Those implants that contain calcium, silicon, and carbon tend to have properties of osseointegration and osseointegration and are discussed in greater detail in this article.

## CALCIUM PHOSPHATE-BASED ALLOPLASTS

Of those alloplastic materials used to augment and replace the facial skeleton, the most promising and well tolerated are the calcium phosphate-based compounds.<sup>8–11</sup> This is because the majority of the human skeleton is composed of calcium phosphate mainly in the form of hydroxyapatite (HA) (Table 2). Owing to their high content in bone, the focus of attention in calcium phosphate-based alloplasts has been with “apatite” forms of this compound.<sup>2</sup> The general formula of apatite compounds is  $\text{Ca}_5(\text{X})(\text{PO}_4)_3$ , where X = fluorine (F), chlorine (Cl), hydroxide (OH), or  $1/2 \text{CO}_3$ .<sup>12</sup>

The calcium phosphate apatite compounds are all bioactive, which means capable of osseointegra-

tion and osseointegration, to varying degrees depending on the chemical composition and preparation being used. In addition, some of these compounds are capable of actually being replaced by bone over time. This process occurs through osseointegration and gradual resorption of the implant itself. The degree of bone replacement with respect to implant resorption can be variable. Bone replacement, however, does not take place by osseointegration whereby new bone is capable of being formed at a nonosseous site. For osseointegration to occur with the use of calcium phosphate apatite compounds, they must be combined with osteoinductive proteins such as osteogenin or bone morphogenetic protein (BMP).

The main types of calcium phosphate apatite preparations used in maxillofacial applications are tricalcium phosphate and hydroxyapatite.<sup>2</sup> Since the mid-1970s, hydroxyapatite has been clinically used in its ceramic form. The process whereby hydroxyapatite is converted to a ceramic form occurs by a process called sintering.<sup>4</sup> Individual HA crystals are heated or sintered to a temperature of 600 to 700°C. This intense heating causes a fusion of the individual HA crystals into a hard, strong, functionally nonresorbable material before implantation. In more recent years, a nonceramic form of HA has been developed which solidifies in vivo, thus enabling intraoperative contouring. A feature that makes these compounds quite attractive.

## Tricalcium Phosphate

Tricalcium phosphate, like hydroxyapatite, is a biocompatible, porous ceramic that is osteoconductive, providing a scaffold for potential bony ingrowth. Unlike hydroxyapatite, however, tricalcium phosphate is resorbable. The porous nature stems from the fact that it is formed from calcium carbonate coral, which is porous with parallel channels and interconnecting fenestrations.<sup>13</sup> The pores allow the ingrowth of bone and fibrous tissue into the implant. Since tricalcium phosphate is resorbable, the osseointegration of bone should eventually replace the alloplastic implant. The problem is that this replacement does not occur in a 1:1 ratio; thus, less bone volume is produced as compared with the volume of tricalcium phosphate absorbed.<sup>2</sup>

Because of this variation in bone volume, the main uses for tricalcium phosphate have been primarily adjunctive by combining them with collagen, glutaraldehyde cross-linked gelatin, and osteogenin, an osteoinductive protein.<sup>13–15</sup> Chapman et al.<sup>14</sup> compared the use autogenous bone grafts with a composite material composed of bovine col-

lagen, calcium phosphate ceramic, and autogenous bone marrow in patients suffering from long bone fractures. Both groups had no significant differences in rates of union, functional measures, or complications apart from a higher infection rate in patients managed with autogenous bone graft alone. If calcium phosphate in combination with collagen can generate a level of strength capable of managing long bone fractures, there use in stress bearing areas of the head and neck, such as the mandible, is possible. In another study, conducted by Breitbart et al.,<sup>13</sup> the use of tricalcium phosphate with osteogenin as an onlay bone graft substitute for the frontal bone of rabbits was examined. The results demonstrated a higher level of bone ingrowth and a higher percentage of mature lamellar bone in the osteogenin-tricalcium phosphate groups. In addition, there was no change in volume, which suggests a 1:1 bone replacement. This study shows promise in the application of a composite material containing tricalcium phosphate as an onlay bone graft substitute. To the best of our knowledge, no implants entirely composed of tricalcium phosphate are specifically approved by the Food and Drug Administration (FDA) for craniofacial reconstruction.

## Hydroxyapatite Preparations

HA makes up the principal mineral component of bone and constitutes 60% of the calcified human skeleton.<sup>2</sup> The chemical composition of hydroxyapatite is  $\text{Ca}(\text{PO}_4)_6(\text{OH})_2$ , and it has been produced synthetically since the early 1970s.<sup>16</sup> At physiological pH, it is the least soluble of the naturally occurring calcium phosphate salts. This is one of the reasons that contribute to the relative resistance of HA to resorption. All forms of HA are biocompatible and do not cause a sustained foreign body response or toxic reaction.<sup>4</sup> Although HA is osseointegrative, there is no evidence that it is osteogenic in the absence of inductive growth factors.<sup>17</sup>

HA can be divided into two general categories: ceramic and nonceramic. The ceramic preparations are known to be nonresorbable *in vivo*, while nonceramic preparations are capable of being resorbed, as they are not sintered.<sup>2</sup>

### Ceramic Hydroxyapatite

Ceramic forms of HA are synthesized through a process of sintering whereby individual HA crystals are heated at 700 to 1300°C to form a solid mass of HA.<sup>2</sup> Ceramic HA is available in two forms: dense and porous.<sup>4</sup>

Dense ceramic HA comes in block and granula form. The block form is not useful in facial plastic surgery due to its inability to be contoured and permit fibro-osseous growth.<sup>2</sup> The granule form is more amenable to contouring; however, there is a problem with stabilization of the implant within its desired site of placement and a lack of mechanical stability until surrounded by fibro-osseous tissue.<sup>18</sup> To address the issues of instability and implant migration, the HA granules have been combined with carrier compounds such as collagen to aid in granule containment.<sup>18</sup> In addition, Koempel et al.<sup>22</sup> examined the use of recombinant human bone morphogenetic protein (rhBMP-2) and its effect on porous hydroxyapatite stability. Their study in rabbits showed enhanced osseointegration, thereby fixing the implant in position against the host–bone interface. The use of these inductive factors greatly accelerates the ingrowth of bone into the pores of HA implants.<sup>2</sup> Apaceram is a synthetic dense form of HA that is being studied for use as an auditory ossicle. Studies are currently being done in Japan with rats to examine the long-term subcutaneous tissue reaction to Apaceram.<sup>24</sup> Apaceram has also been used in Japan to fill surgical skull defects with good results.<sup>25</sup>

Porous ceramic HA permits bony ingrowth if the pores have a minimum diameter of 200  $\mu\text{m}$ . The porous pattern is based on marine coral of the genus *Porites*. The calcium carbonate of the coral is chemically converted to HA, while maintaining the original porous structure of the coral.<sup>2</sup> An advantage of porous HA is the ability for it to undergo fibro-osseous ingrowth, fixing the implant to the recipient site within several weeks. The porous granules appear to be less susceptible to migration than the dense granular HA.<sup>23</sup> Interpore International produces two forms of porous ceramic HA: (1) Interpore 200, with 200- $\mu\text{m}$  pores, and (2) Interpore 500, with 500- $\mu\text{m}$  pores.

The addition of human marrow cells derived from cultured bone to porous hydroxyapatite ceramics was deposited in mice, showing the formation of a thick layer of lamellar bone with active osteoblasts lining many of the pores. This combination of bone marrow derived cells to an alloplastic implant such as porous HA gives the implant osteogenic potential.<sup>19</sup> Porous ceramic HA was also examined for the use of treating calvarial defects in the maturing skeleton. The use of Interpore 500 was effective in treating calvarial defects of the neonatal swine. Bone growth into the inorganic matrix of the implant provided complete osseous union (osseointegration) and volumetric bone gain with concurrent resorption of the implant.<sup>20</sup> In a long-term follow-up study (average follow-up period 7.3 years) of porous block HA used as a

synthetic bone graft in orthognathic surgery and craniofacial augmentation, there was a high percentage of success and efficacy with its use in the mandible and maxilla. The only exception were its use for alveolar cleft grafting that had a 100% failure rate and midpalatal grafting that had a 14% failure rate due to the lack of soft tissue coverage of the implant in the area of the palate.<sup>21</sup>

### Nonceramic Hydroxyapatite

Hydroxyapatite cement (HAC) (BoneSource HAC, Leibinger, Dallas, TX) is a nonceramic cement that has certain qualities that make it unique from ceramic HA. The formation of HAC occurs in vivo with an isothermic environment at physiologic pH. Tetracalcium phosphate and dicalcium dihydrate in the presence of an aqueous environment form of HA. The two reactants are mixed with water to form a paste that can be applied and contoured to the desired result. The paste will set to cement within 15 minutes, and the resection to HA is completed within 4 hours.<sup>4</sup> It is imperative that the recipient site be devoid of blood and aqueous material so that the reaction is not affected. If the cement contacts an aqueous environment before being converted to HA (4 hours), the cement will set in particle form and lead to portions of the implant resorbed with a loss of implant volume.<sup>2</sup> HAC does undergo osseointegration and osseointegration like ceramic HA; however, a unique quality is the ability of HAC to undergo implant resorption and bone deposition in a 1:1 ratio, thus without a loss of volume at the recipient site.<sup>4</sup> The compressive strength of HAC is within the range of 60 megapascals (MPa), which is relatively strong; however, it has limited shear resistance and should not be used for stress-bearing applications<sup>26</sup> without additional hardware.<sup>27</sup>

HAC was successfully used to augment the supraorbital ridges of dogs. Two groups of dogs were used: (1) augmentation with HAC alone, and (2) augmentation with HAC wrapped within a collagen membrane to facilitate application. Osseointegration and osseointegration were demonstrated when HAC was used alone, but when HAC was placed within the collagen membrane, no osseointegration was noted—just a fibrous union of bone to implant, and no osseointegration as well.<sup>28</sup> Although the collagen-wrapped HAC did have a solid bond to the underlying bone, when HAC was used alone not only was there stability of the implant but also progressive replacement of the implant by bone.<sup>28</sup> Friedman et al.<sup>29</sup> found that after 6 months, new bone accounted for 5% of implant volume, and at 18 months, this value increased to 63%.

**Table 2. Composition of Bone**

<i>Component</i>	<i>%</i>
Water	12.2
Organic constituent	24.6
Mineral constituent (mainly hydroxyapatite)	57.9
Trace components	5.3

From Costantino et al.<sup>2</sup>

The use of HAC in craniofacial reconstruction of the developing craniofacial skeleton was examined by Lykins et al.<sup>29</sup> These investigators performed fronto-orbital craniotomies on 14 kittens and compared reconstruction using an orthotopic bone flap versus using HAC alone. Each group had seven kittens, and another seven kittens were used as controls whom did not have craniotomies performed. The extent of the craniotomies extended across the coronal suture line in order to create the greatest growth disturbance possible. Grossly, morphological studies showed excellent contour reconstruction in both groups; however, when craniometric analysis was done, a wider skull was seen in one of the HAC kittens as compared with the other two groups. The widened area was at the area of the plated coronal suture, which would not be surprising, because if growth is impeded in the area of a suture (as in this case), growth tends to occur in a direction parallel to the involved suture.<sup>29</sup> This study demonstrated that although HAC appears to be a safe alternative in the reconstruction of the developing feline, its application to humans requires more evaluation, as the pattern of the growing skull in felines differs from that in humans. The kittens in this study had reached 70% of their adult brain size, whereas humans reach 80% of their adult brain size at 2 to 3 years of age.<sup>29</sup>

HAC (BoneSource), which has been used experimentally as an onlay implant for supraorbital and malar augmentation in rats, was recently cleared for clinical use in facial skeletal augmentation.<sup>27</sup>

### CALCIUM SULFATE-BASED ALLOPLASTS

Calcium sulfate hemihydrate, otherwise known as plaster of paris, was first used as a bone graft substitute in 1892 to fill tuberculous cavities in the long bones.<sup>30</sup> The composition of plaster of paris is partially dehydrated calcium sulfate, which is made by heating gypsum (calcium sulfate dihydrate) such that it loses three-fourths of its bound water to form a calcium sulfate hemihydrate ( $\text{CaSO}_4 \cdot 1/2\text{H}_2\text{O} + 1/2\text{H}_2\text{O} \rightarrow \text{CaSO}_4 \cdot 2\text{H}_2\text{O}$ ).<sup>2</sup>

Calcium sulfate hemihydrate is mixed with water to form a contourable paste that sets in approximately 5 minutes through an exothermic reaction.

The heat released from this reaction is not significant enough to cause tissue damage.<sup>2</sup> Once the plaster of paris has set, the tensile strength achieved is 24 MPa, which is less than the amount achieved by methylmethacrylate or HAC: 70 MPa and 60 to 70 MPa, respectively. In addition, its inability to resist flexural posturing causes it to be prone to fracture in shear-loaded situations. Thus, plaster of paris is not appropriate for stress-bearing applications.<sup>2</sup> Another limitation of the compound is that it does not set to a stable form in the presence of excess aqueous fluid. This feature is seen with HAC as well; however, in the case of plaster of paris, if the compound is exposed to water a second time, it softens and becomes structurally weak and unstable.<sup>2</sup>

The use of calcium sulfate hemihydrate was examined in frontal sinus obliteration by Beeson in 1981.<sup>31</sup> In addition, Pecora et al.<sup>32</sup> found calcium sulfate potentially useful as a graft material for sinus augmentation; however, this clinical report looked at only two cases, thus further evaluation of its use in this capacity would be necessary. Studies done that report efficacy in the use of calcium sulfate as a graft material for cranial defects,<sup>33</sup> but these have lacked objective measurement of the compound's contour stability, which is an important issue to consider in facial plastic and reconstructive surgery.

The main uses of calcium sulfate have been in the field of orthopaedics for casting extremity fractures; more recently, it has been approved by the FDA as part of a composite implant known as Hapset.<sup>2</sup> Hapset is composed of porous ceramic hydroxyapatite granules and calcium sulfate. The reasoning behind using these two compounds is that ceramic HA granules are known to be difficult to stabilize within the desired implant area, so calcium sulfate has been added to bind the HA granules together for better stabilization. By adding stability, the implant is held in place until bone ingrowth can occur. The calcium sulfate eventually resorbs over a period of time. To the best of our knowledge, Hapset is the only FDA-approved use of calcium sulfate.

## CALCIUM CARBONATE-BASED ALLOPLASTS

Calcium carbonate-based implants are derived from marine coral within the genus *Porites* similar to calcium phosphate. The structural difference is that calcium carbonate is derived from unaltered marine coral, whereas calcium phosphate has been biochemically converted from its compound of origin, calcium carbonate. Another functional difference between these two marine coral-derived im-

plants is that ceramic HA implants are nonresorbable, while calcium carbonate implants are progressively resorbed over time and replaced with fibro-osseous tissue when implanted subperiosteally<sup>2</sup> (Table 2). As a result of this resorption, the site of implantation may undergo postoperative contour changes over time.<sup>2</sup> Both undergo osseointegration and osseosynthesis; however, once bony ingrowth into the implant pores is complete, osteoclasts begin to absorb the implant, and osteoblasts deposit bone.<sup>31</sup> To the best of our knowledge, there has not been a histomorphometric analysis of the fibro-osseous tissue replacement of calcium carbonate implants, but the evidence suggests that this replacement occurs more rapidly than that seen with porous ceramic hydroxyapatite (Interpore 200 or 500).<sup>2</sup> The combination of resorptive ability and rapid fibro-osseous replacement makes calcium carbonate a sound implant choice in situations such as orthopaedic surgery, where contour loss is not as important as osseous replacement. In addition, contour applications of pediatric craniofacial skeleton, where revisions are commonly done and bone remodeling is rapid, would benefit from an implant such as calcium carbonate.<sup>2</sup>

Two shortcomings of calcium carbonate implants are their inability to withstand flexural stresses and its lack of contour maintenance over a period of time. When used in stress-bearing applications, such as mandibular reconstruction, a reinforcing device is necessary as an adjunct at least until fibrous replacement can occur. The issue of contour maintenance occurs in the application of the adult non-stress-bearing craniofacial skeleton. In these cases, an implant that does not resorb or is replaced in a 1:1 fashion (i.e., HAC) by fibro-osseous tissue is more beneficial. Long-term contour stability is of more importance in the adult than in the pediatric population, where "revision procedures are the rule rather than the exception."<sup>2</sup>

## SILICON-BASED ALLOPLASTS

Silicon-based implants used in facial plastic surgery are composed of either silicate (silicon dioxide) or polymers of dimethylsiloxane. Silicate and silicone are two distinct materials, although both are derived from the element silicon. Silicate is silicon dioxide and forms a hard substance that can be molded into various forms such as glass or sand. Silicone is a polymer of dimethylsiloxane and is a well-known implant in facial plastic surgery. Dimethylsiloxane is composed of silicon, oxygen, and two methyl side groups attached to each silicon-oxygen combination. This material takes on a rubbery consistency, and alone has no ability to os-

seointegrate or osseointegrate bone. By contrast, only certain silicate-based compounds are potentially capable of directly bonding to bone. In order to be bioactive, these silicate-based materials are combined with other compounds to alter its physical properties to achieve bioactivity. Although silicon is not found in the human body, such as HA, it still is well tolerated and does not demonstrate any clinical carcinogenic or immunogenic potential.<sup>2</sup>

Silicate has been used as the key component in two substances that have applicability to facial plastic and reconstructive surgery: (1) bioactive glass, and (2) glass-ionomer cement. Silastic is the most common silicone implant used in facial plastic surgery. Its main use has been with facial skeletal augmentation.<sup>27</sup>

### Bioactive Glasses

Bioactive glasses are composed of varying combinations of sodium oxide, calcium phosphate, and silicate, depending on the desired use of the implant. The mechanism by which the bioactive glass binds to bone is quite interesting. A microenvironment exists within a silica-rich gel at the implant surface. Within this gel, the calcium and phosphate of the implant form HA, which interacts with bone surface substances, such as collagen and glycoproteins, to form a bond between the implant and bone (osseointegration). Despite the ability to bind to bone, the implant is not replaced by bone over time.

The main use for bioactive glass has been middle ear ossicular reconstruction. In the studies done with bioactive glass, there has been no evidence of implant extrusion; however, when failure has occurred, it has been by implant degradation.<sup>2</sup> They perform equally as well as HA ossicular implants.

The main disadvantages of bioactive glasses are their difficulty with fixation and intraoperative implant contouring. The granule form is unstable until ingrown by fibro-osseous tissue, and the block form cannot be screw stabilized, as it has a tendency to shatter during creation of screw holes.<sup>2</sup> Recent studies have examined a novel resorbable bioactive glass that was used to repair mandibular defects in rats.<sup>32</sup>

### Glass Ionomer Cement and Solids

Glass-ionomers are hybrid compounds of organic and inorganic components. They are synthesized from a two-component reaction<sup>2</sup> of a calcium-aluminum fluorosilicate glass and an aqueous solution of polycarboxylic acid. Through a series of

reactions, a composite of silicate, calcium, and aluminum ions dispersed throughout a porous polymeric carbon matrix is formed. Unlike porous ceramic HA, which has a uniform pore size, glass ionomer has an interconnecting system of micropores (1 to 10  $\mu\text{m}$ ) and macropores (100 to 300  $\mu\text{m}$ ).<sup>2</sup> The manner in which glass ionomer osseointegrates with bone is similar to bioactive glass, except that aluminum ions and crystals are found at the interface, in addition to calcium phosphate. Glass ionomer implants are nonresorbable.

There is a porous, granular form of glass-ionomer, Ionogran, which has osseointegrative properties and can be used to fill osseous defects. One drawback is that this compound has no intrinsic structural stability until fibro-osseous ingrowth has occurred, similar to granular ceramic HA. Ionomeric cement is another form of glass-ionomer that is capable of being intraoperatively contoured and sets in situ.<sup>33</sup> The cement forms from combining a polyalkenoic acid with a calcium aluminosilicate glass powder which are kept in two separate chambers. When ready for use, the acid and powder are mixed forming a cement via an exothermic,  $\text{CO}_2$ -producing reaction. The cement can be applied and sets in 5 minutes into a water-insoluble solid. Until setting occurs, however, any liquid can dissolve this material, thus the implant area should be kept dry until setting is complete. In a study conducted by Jonck et al., it was demonstrated that the cement has a compressive strength and modulus of elasticity comparable to cortical bone.<sup>2,34</sup>

Ionomeric cement has been used in the craniofacial skeleton in calvarial reconstruction and otologic surgery. Baier and Geyer and colleagues showed efficacy in the treatment of cranial base defects with ionomeric cement.<sup>36</sup> Forty-four patients underwent skull base reconstruction, and in only one was there dislocation of the implant which necessitated revision surgery. There were no cases of cerebrospinal fluid (CSF) leaks and plasma aluminum concentrations were not significantly elevated as compared with controls. In another study, ossicular chain reconstruction was done in baboons using ionomeric cement both as an ossicular prosthesis and as a fixation device.<sup>35</sup> The superstructure of the stapes was removed along with the incus and malleus head. A columella of hardened ionomeric cement was placed between the stapes footplate and malleus handle and fixated with freshly mixed ionomeric cement. The columella underwent spontaneous epithelialization and demonstrated middle ear compatibility and biostability. Unfortunately, the commercial withdrawal of ionomeric cement in May 1995 was done due to four cases of aluminum encephalopathy reported in the literature.

## Silicone

Silicone implants used in facial plastic surgery are derived from a polymer of dimethylsiloxane. The implants possess a rubbery consistency and are relatively inert. Despite this inertness, silicone implants become enveloped within a fibrous capsule; however, because silicone is not itself capable of osseointegration, the fibrous capsule aids in implant fixation.<sup>37</sup> Because this capsule develops over time, initial fixation of the implant should be attempted to avoid migration.<sup>27</sup> Some suggested methods are by supraperiosteal placement in a defined pocket, nonresorbable sutures, or metal screws.<sup>27</sup>

Silicone implants come in block form and pre-molded implants.<sup>37</sup> The main use of silicone in facial plastic surgery is for facial skeletal augmentation, more specifically the chin and malar eminence.<sup>27,37</sup> Preformed shapes exist for nasal, malar, and chin augmentation, and due to their easy compressibility, they can be more easily inserted through small incisions.<sup>27,37</sup>

The main shortcoming of silicone implants has been its association with underlying bone resorption.<sup>27</sup> It is possible that improper fixation of the implant will lead to long-term implant motion, causing inflammation sufficient to cause bony erosion and subsequent implant migration.<sup>37</sup>

## MISCELLANEOUS ALLOPLASTS AND ADJUNCTS

### Polyethylene

Polyethylene polymers are carbon-based implants composed of high-density ethylene that is fused into a porous solid material by a sintering process.<sup>27</sup> These implants are used mainly for facial skeletal augmentation, and possess pore sizes within the range of 100 to 300  $\mu\text{m}$ , which aid in tissue ingrowth and implant fixation. One point to stress is that some of the tissue ingrowth is vascular; thus adding to infection resistance and potential salvage of the implant in the face of exposure.<sup>27</sup> Foreign body reaction to polyethylene is minimal and long-term stability has been achieved.<sup>37</sup>

Frodel and Lee<sup>38</sup> examined the use of high-density polyethylene implants in the repair of a variety of facial skeletal deformities. Thirty-four patients with defects ranging from the temporal fossa to the maxillary region underwent a repair. Of this group, four patients had implant exposure with the rest free of complications. The study demonstrates the versatility of high-density polyethylene in repairing facial skeletal deformities (frontocranial, temporal fossa, malar, calvarial); however, the com-

plaint is difficult to contour due to its rigid nature. Lykins et al.<sup>37</sup> commented on a study by Rubin<sup>39</sup> that demonstrated a higher failure rate with polyethylene occurring in the nose and ear. Romo et al.,<sup>40</sup> however, showed a high success rate in the nasal reconstruction of 187 patients, 121 of whom were revisions. The study group had a complication rate of 2.6%, which consisted of patients with a predisposition for poor healing. No evidence of implant extrusion or skin erosion occurred in the study group. High-density polyethylene implants demonstrated fibrovascular ingrowth and were well tolerated.

Other carbon-based alloplastic implants have been used in facial plastic and reconstructive surgery: polymethylmethacrylate (PMMA), Hard Tissue Replacement (HTR) Polymer (HTR Sciences, Norwalk, CT), and polytetrafluoroethylene. Further information regarding these compounds was purposely not included because of their lack of increased efficacy when compared to the other alloplastic implants described earlier. PMMA has served a greater role in the field of orthopaedics, and the extreme exothermic reaction associated with its setting process has proved deleterious to adjacent bone and soft tissue even with vigorous irrigation with cool saline.<sup>41</sup> HTR Polymer has shown promise in some studies; however, conflicting results regarding its efficacy suggest that further evaluation is needed before its can be used routinely. Polytetrafluoroethylene in the form of Proplast had been used successfully for augmentation of the craniofacial skeleton, but complications occurring in failed temporomandibular joint (TMJ) reconstructions has led to its withdrawal from the market in the United States.

### Bone Induction Proteins

Autogenous bone grafts have traditionally been the gold standard graft for skeletal reconstruction. This is because of their ability to stimulate new bone formation at their site of implantation (osteogenesis), as well as osseointegrate with the surrounding bone. Some drawbacks, however, of autogenous bone grafts are donor site morbidity, contour irregularities, and unpredictable postimplant resorption. These shortcomings spawned the trend of composite grafts that use alloplastic implants, which avoid the donor site morbidity of autogenous bone grafts, in combination with bone morphogenetic proteins (a.k.a. osteogenic proteins) such as BMP-3 (Osteogenin), which accelerate the deposition of new bone at the recipient site. The osteoinductive properties of demineralized bone matrix has been demonstrated in the past.<sup>43</sup> Since that

time, further purification of demineralized bone matrix has led to the isolation of seven bone morphogenetic proteins, BMP-2 to BMP-8. Of these, BMP-3 (Osteogenin) has demonstrated the highest bone inductive activity.<sup>42,44</sup> When used with a non-resorbable implant such as hydroxyapatite, bone morphogenetic proteins can stimulate bone growth into the implant, whereas the implant itself helps maintain volume to prevent any loss of contouring. In addition, it was shown that a composite implant with osteogenic proteins such as BMP-3, accelerate the degree of mature bone growth into the implant when compared to using implant alone.<sup>42</sup>

Breitbart et al.<sup>42</sup> examined the possibility of using a resorbable alloplastic implant, tricalcium phosphate, which would alleviate the problem of having a permanent foreign body at the implant site as in the case of nonresorbable hydroxyapatite. Three weeks into the study, 69% of the implant was occupied by new bone and greater than half of the tricalcium phosphate was resorbed.<sup>42</sup> Although not demonstrated in this study, it is reasonable to assume that the deposition of bone stimulated by BMP-3 (Osteogenin) will eventually replace the recipient site with no residual implant over time. If this process could be achieved so that new bone formation occurred in a 1:1 ratio with implant resorption, this would permit defect repair without a loss of volume. Follow-up evaluation at 3 and 6 months in the study conducted by Breitbart et al.<sup>42</sup> demonstrated no loss of volume at the implant site; however, whether this volume maintenance would be present until the entire implant was resorbed is unknown. Although tricalcium phosphate appears to have some benefit over ceramic HA, there still exists difficulty with contouring intraoperatively. An interesting study could look at the use of HAC, which can be contoured in situ and is also replaced by bone in a 1:1 ratio, in combination with osteogenic proteins such as BMP-3 (Osteogenin).

## SUMMARY

The skeleton of an appropriate bone substitute is a decision based on an individual basis. The search for the ideal implant material continues; thus, facial plastic and reconstructive surgeons are called upon to use their clinical judgment in determining which implant material will be most suitable for each patient. Current trends in combining alloplastic implant materials with osteogenic proteins have shown particular promise. With continued advances in medical and biochemical technology, the search for the ideal implant material will soon be completed.

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