Subantral Augmentation with Human Allograft Materials and Simultaneous Endosseous Root-form Implant Placement: A Case Report with Clinical Observations

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Running Head: Subantral

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Abstract

Four endosseous root-form implants were installed with simultaneous subantral augmentation utilizing a 1:1 mixture of freeze-dried demineralized bone and naturally porous biomaterial (Osteomin®, Pacific Coast Tissue Bank, Los Angeles, CA). A three-month biopsy of the allograft revealed considerable resorption of the graft material with simultaneous generation of new bone via both conductive, osteotropic and inductive physiology. There was no presence of giant cell involvement or inflammatory reaction. A one-year post-loading CAT scan revealed very dense bone with complete fusion to lateral and inferior walls supporting four well osseointegrated fixtures.

KEY WORDS: endosseous root-form implants, allograft, naturally porous biomaterial (NPB), osteoinduction, osteoconduction, osteotropic.

Introduction

Limitations in the vertical and horizontal dimensions are among the most serious challenges confronting the oral implantologist in the maxillary arch.[1] This situation is exacerbated in the posterior regions as the edentulous jaw atrophies and the sinuses pnuematize. Coupled with this compromise in quantity is the impoverished quality of bone in this region. Composed of fine trabecular with little or no cortical crest, it is the least dense bone of the body.[2-4] These severe anatomical limitations can prevent placement of endosseous root-form implants of sufficient length for successful prosthodontic loading, potentially leading to pathologic fracture of the implants or of the oral anatomy itself.[4-5]

Subantral augmentation is a means of increasing the quantity of bone in the sinus region in order to use longer implants than the atrophied jaw could normally accommodate. This paper presents a case report of a subantral augmentation procedure utilizing an allograft mixture of freeze-dried demineralized bone and mineralized human thermal ash, followed by simultaneous endosseous root-form implant placement.

Literature Review

Mandibular and maxillary augmentation utilizing autogenous bone and synthetic bone substitutes with and without endosseous implant placement is widely reported in the

literature.[6-24] Research shows that the use of these several different grafting materials, including autogenous grafts, results in a physiologic breakdown of the graft material followed by the generation and deposition of new bone. This process is called osteoconduction.

Many applications of the use of freeze-dried demineralized bone (FDDB) to repair osseous defects is also extensively documented.[15-21] FDDB has been shown to induce osteogenesis by transforming undifferentiated mesenchymal cells into chondroblasts, even when implanted into nonskeletal tissue.[22] This process is called osteoinduction. Several applications of this allograft material have been reported in conjunction with endosseous root-form implants.[23-27]

The literature attests to the safety and efficacy of subantral augmentation procedures in conjunction with implant therapy.[4-5, 7-8, 10-12, 14, 24-25, 29-31] Various graft materials have been used for this procedure, including harvested autogenous bone,[5, 14, 24, 30] allogeneic demineralized bone,[5, 7] allogeneic irradiated mineralized bone,[5, 31] irradiated cartilage,[5] tricalcium phosphate,[5, 19, 28-29] natural coral,[5] polymers,[5] and hydroxylapatite (HA).[5, 7, 10-11, 19, 29] While the usual method entails augmenting the site and placing the implant in the same procedure,[4-5, 7, 19, 28-29, 31] an alternate two-stage approach with an intervening healing period between grafting and implant placement when using harvested autogenous bone grafts[7, 30] or when the alveolar crestal bone is less than 3-1

4mm in height, has also been reported.[29]

Various applications and increased clinical interest in naturally porous biomaterials (NPB) as xenografts have also been documented.[32-37] With current technology in processing and nitrogen analysis, these anorganic xenografts will probably prove to be non-inflammatory. However, the number of papers published on the osteoconductive nature of HA, coupled with the apparent link of micromorphology to phenology, suggest it would make sense to use NPB from the same species. This is currently under investigation by others.

There are currently two commonly accepted processes for the resorption of HA. The first is aqueous dissolution of the soluble components. The second has been demonstrated as a form of cellular phagocytosis and intracellular encapsulation.[30] Hypothetically one could also include physiologic degradation resulting from stress-induced remodeling at the implant interface. Current theories on the actual physio-chemical processes involved in osteoclastic breakdown are still incomplete.

An absorptive, osteoinductive process from circulating factors in the plasma of larger primates has been documented.[39] In this study, ectopic osteogenesis occurred in non-skeletal tissue through an inductive process from porous, coralline hydroxyapatite (genus Goniopora). The average porosity of the hydroxyapatite in this study was 600 micrometers.

In another study involving FDDB, Gendler suggests the pore size of 500-600 micrometers

may, in some way, influence intra-cellular micro pressures, and may contribute to endochondral osteogenesis observed in the adipose tissue of lab rats.[40] This researcher further posits bone morphogenic protein (BMP) on the surface of the FDDB was the major contributing influence in undifferentiated mesenchymal cells differentiating into chondrocytes, and eventually into osteoblasts, providing adequate vascularity and oxygen tension greater than 30% is present.

The porosity of HA and the associated three-dimensional lattice significantly influenced whether or not osteoconduction occurred in another study.[41]

Materials and Methods

The patient was a partially edentulous 45-year-old Caucasian female [Fig. 1] with no remarkable past or present health history.

Conventional implant reconstruction in the posterior maxilla, and the posterior mandible was successfully performed on the right side at an earlier date [Fig. 2A]. The maxillary left edentulous ridge was atrophied to the point that conventional implant placement and prosthetic reconstruction could not be performed without subantral augmentation.

First Stage Augmentation & Fixture Placement

Pre-surgical preparations included medical, dental and radiographic evaluations, and

basic dental therapy to alleviate pre-existing medical-dental problems. A signed patient consent form was obtained before proceeding.

The patient was started on 500 mg of penicillin V K (tabs 2 stat 1 quid until gone) 24-hours prior to the surgical appointment.

On the day of the surgery, the patient was lightly sedated with 5mg of diazepam orally, then draped with sterile surgical barriers. The left posterior quadrant of the maxilla was anesthetized via local infiltration with 1:50,000 epinephrine in a 27-gauge syringe.

Thirty minutes prior to the surgery, a mixture of FDDB (Dembone™, Pacific Coast Tissue Bank, Los Angeles, CA) in two particle sizes (2.5cc 50-125 microns and 2.5cc 250-500 microns) was saturated in sterile saline. After approximately 15 minutes, the excess fluid was drained and 1cc of lincomycin (300mg/ml) was added. This was allowed to sit for at least 10 minutes, then 5cc of bone-derived human thermal ash (Osteomin™, Pacific Coast Tissue Bank, Los Angeles, CA), was added. This NPB anorganic matrix, which had been steam-pressure and high-heat processed to completely remove the organic fraction (confirmed by Kjeldahl nitrogen analysis with values in the range of 2-16 ppm), was the ideal particle size (50-500 microns) and micro-porosity to function as a resorbable from of hydroxylapatite [Figs. 3, 4].[42-44] Sufficient sterile saline was added to saturate the completed mixture, which will be called Allograft 1 in this paper.

A direct, full thickness midcrestal incision with a #15 Bard-Parker™ blade was made

through the mucoperiosteum to the crest of the ridge, with vertical release incisions at the mesial and distal aspects. Full thickness reflection of the buccal and palatal tissues exposed the atrophied ridge and maxillary wall. A modified Caldwell-Luc incision was prepared through the lateral wall up to, but not including, the Schneiderian membrane. This mucoperiosteal membrane was then reflected from the floor and surrounding walls without perforation.[5, 30]

Sequentially using slow-speed (600-800 rpm), internally irrigated drills increasing in diameter, four osteotomies were performed through the atrophied ridge, perforating the floor of the sinus into the newly open space below the pre-existing antrum. The first osteotomy was 16mm in length, with 12mm within existing bone and the last 4mm within the augmentation material. Osteotomies two, three, and four had 8mm, 4mm and 2mm of bone before perforations respectively. This allowed the author to evaluate simultaneous fixture placement of all four clinical situations in the same case.

Allograft 1 was introduced into the augmentation area using a modified stasis syringe until the receptor site was 50% full. The root-form endosseous implants selected for this case were an HA-coated ledged or fluted design (Micro-Vent® Implants, Dentsply/Implant Division, Encino, CA), because the normally spongy quality of bone in this area must develop a stress-bearing surface adjacent to the implant if the fixture is to remain stable and transmit a physiologic load to the interface of the bone.[28] The horizontal ledges or flutes allow ingrowth of the Type IV bone in this area to support vertical loading. The implants were introduced through the osteotomies [Fig. 5A] and into the augmentation

area [Fig. 5B].

After the fixtures were placed, the remaining Allograft 1 mixture was firmly packed into the augmentation area. The Caldwell-Luc opening was then repaired using a strip of perforated freeze-dried demineralized laminar bone (Pacific Coast Tissue Bank, Encino, CA). After repositioning the soft tissues, primary closure was attained using 3-0 silk sutures [Figs. 2A, 5A-B]. The site was allowed to heal for three months.

Second Stage Uncovering & Biopsy

A radiographic examination revealed no peri-implant radiolucency at the three-month uncovering appointment [Fig. 6]. With a #15 Bard-Parker™ blade, a midcrestal incision and full thickness reflection exposed the superior aspects of the implants. The surgical cover screws were removed, and the fixtures were torqued to 28 Newton centimeters to assure integration had occurred. There was no evidence of pain or mobility, and the implants elicited a crisp ring when tapped with a metal instrument. These provided indications of what Branemark termed clinical osseointegration, or a "direct structural and functional connection between ordered living bone and the surface of a load-carrying implant."[45]

A 16mm core sample biopsy of the augmented area was taken in two 8mm blocks distal to the last implant [Fig. 6A]. Titanium healing collars were threaded into the implants and

the soft tissues were sutured around them using 3-0 black silk sutures [Fig. 6].

Histologic analysis of the biopsy showed considerable resorption of the FDDB [Fig. 7A]. There was a large amount of new Type III trabecular bone with multiple osteocytes [Fig. 7B]. In several areas of the biopsy, there was evidence of active osteogenesis with a large number of osteoblasts and osteoid being deposited on the surface of mineralized bone trabeculae [Fig. 7C].

Multiple particles of NPB were present [Figs. 8A, 10A, 11A, 14A], the majority of which were surrounded by new bone. However, some were also free lying [Fig. 9C]. New bone was very intimately apposed to the surface of the NPB [Figs. 8A, 10A, 11A] and there was no evidence of inflammatory infiltrates or giant cell reaction [Figs. 7-14]. In some areas there was evidence of connective tissue and new bone ingrowth inside the particles of NPB [Fig. 10A]. This leads the author to believe a reduction of the percentage of NPB should be implemented in future cases to approximately 25% by volume.

Unresorbed particles of FDDB could still be seen side-by-side with new trabecular bone [Figs. 7A, 9A]. There was evidence of active osteogenesis with multiple osteoblasts and deposition of osteoid on the surface of mineralize trabecular bone and particles of OsteominTM [Figs. 8A-8B].

Prosthetic procedures commenced two weeks after placing the titanium healing collars, and the implants were loaded with an implant-supported fixed partial denture.

Six-month Follow-up

After six months of full prosthetic loading, a postoperative radiograph [Fig. 15] demonstrated no bone loss and maintenance of the Type III to Type IV quality graft. To further demonstrate ideal quality and complete fusion of the newly generated bone to the exposed walls of the maxillary antrum, the patient was submitted for computer radiography [Figs. 16, 17].

Discussion

Perhaps the most significant observation histologically in this case report is the relatively rapid resorption of Allograft 1, and its apparent replacement by the patient's bone. This physiologic process could occur in one of two ways, or perhaps in both. First, if active osteoclasts are present in the osteogenic centers, Allograft 1 could be replaced by the classic physiologic "creeping substitution." This type of physiologic breakdown followed by deposition of new bone (i.e. osteoconduction) has been documented in many publications using several different grafting materials, including autogenous grafts. This first process requires the presence of active osteogenic cells.

The second has been termed "anchorage dependent cell differentiation."[45] This is an increased affinity of circulating polypeptides, consisting of bone morphogenic protein (BMP), platelet-derived growth factor (PDGF), and insulin-like growth factor-I (IGF-I).[46]

These may, in some way, link the calcium phosphate matrix of the highly mineralized NPB surface and then, in turn, induce cellular differentiation within the extracellular matrix (i.e. osteoinduction and direct bone formation).

Two factors which may contribute to this phenomenon are the morphology and porosity of the graft material. El Deeb et al. suggest that homoepitaxial crystallization in a hypertonic solution of adjacent osteoblasts seems to be greatly influenced not only by three dimensional lattice work, but also by the high degree of mineralization.[41]

The issue of highly mineralized surface may in some way contribute to the affinity of the skeletal surface to circulating plasma proteins associated in the phenotypic expression of condensing connective tissue cell types. If conditions are favorable, then this mineralization of HA surface would either attract circulating growth factors, or bone morphogenic proteins (BMP), or both. In turn, it would induce the differentiating cells to become osteogenic potential cells. Burwell uses the term osteotropic material to describe this physiologic process.[47]

NPB, being of human origin, would therefore have the ideal three-dimensional lattice work and mineralized character to influence and create the most ideal environment for both physiologic processes. Studies on lab animals have been initiated to confirm this hypothesis and contradict the findings of Jensen et al.[31] As a result of these histologic findings, the author has reduced the volume and particle sizes of NPB to 25% by volume

and 45-125 microns in subsequent other cases not related to this paper (Allograft 2).

It should be noted that the Type III to Type IV quality bone produced by NPB and FDDB respectively in other cases does not appear to be significantly different from the quality of bone produced by Allograft 1 in this individual case report. However, controlled comparative studies should be conducted to answer this question more fully.

The importance of engaging available cortical bone is a well documented principle for achieving and maintaining osseointegration of root-form endosseous implants.[3, 49-56] This underscores the importance of selecting the appropriate endosseous root-form fixture design - screw, basket, or ledged - to make maximum use of available bone, regardless of bone quality. In areas where cortical bone can not be ideally engaged, HA-coated designs, such as the smooth cylinder, have been shown to achieve a greater percentage of bone/implant contact, greater interfacial shear strengths, and a faster healing rate than non-coated implants.[57-58] The implant system (Spectra-System®, Dentsply/Implant Division, Encino, CA) used in this case provides all four body designs.[56]

What is significant, on the other hand, is the histological evidence of Allograft 1's resorption followed by deposition of new osteoid and connecting trabeculae joining the two different particles. This raises the question of whether combining this allograft with simultaneous placement of implants, followed by a three-month uncovering, will reduce

the time believed necessary to restore these crippled patients, as this individual case suggests. Such findings would offer tremendous advantages to the oral implantologist, and warrant future investigative studies in this area.

Since this case, eight similar cases have been uncovered and loaded in the 3-4 month post-augmentation procedure and followed for a 3-6 month period of time. No ill effects have been clinically observed in any of those cases. This not only further suggests a reduction in the time factor and underscores the need for further research in this area, but also suggests that earlier stimulation to the maturing graft and newly formed bone may enhance the quality of the ultimate result and prevent significant marrow formation so characteristic of this region of the skull. Controlled studies are also needed in this area to confirm these observations. The findings reported in this paper should be considered empirical. Long-term controlled studies must be conducted before final conclusions are drawn.

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Legends for Illustrations

FIGURE 1: Preoperative panoramic radiograph, dated 7/2/90.

FIGURE 2: Panoramic radiographic dated 8/16/91 showing: (A) post-reconstruction of the right quadrant using conventional implant dentistry; (B) postoperative augmentation and simultaneous implant installation.

FIGURE 3: 100 power Scanning Electron Microscope view of a section of human-derived NPB. Note multiple haversian systems, Volkman's canals, and lacunae, presenting its unique porous morphology.

FIGURE 4: 16,000 power Scanning Electron Microscope showing unique microstructure of human-derived NPB.

FIGURE 5: Close-up radiograph view dated 5/20/91 showing: (A) pre-existing lamina dura outlining the old floor of the antrum; (B) new elevated, grafted floor.

FIGURE 6: Close-up radiographic view dated 5/28/91. Note area of biopsy removal tagged by injection of pure human-derived NPB.

FIGURE 7: Three-month human biopsy of graft with H & E stain showing: (A) FDDB

particle; (B) new bone trabeculae; (C) resorbing component of human-derived NPB.

FIGURE 8: Close-up view of three-month human biopsy of graft with H & E stain showing: (A) particle of human-derived NPB; (B) particle completely surrounded by new forming trabeculae.

FIGURE 9: Human biopsy with H & E stain showing: (A) FDDB particle surrounded by new forming osteoid (B) connected to resorbing particles of human-derived NPB.

FIGURE 10: Human biopsy with H & E stain at three months revealing large island of human-derived NPB not associated with FDDB, apparently connected by a rich cellular osteoid.

FIGURE 11: Panoramic radiograph dated 1/27/92, 6 months in function. The graft has remained intact and the fixtures lack peri-implant radiolucency, indicating osseointegration has been maintained.

FIGURE 12: CAT scan, one year in function, lateral view. Note the area of argumentation surrounding the four fixtures.

FIGURE 13: CAT scan, one year in function, multiple horizontal sections, demonstrating complete fusion of newly formed bone to both the lateral walls and the implants at all

levels. The bone quality and type is very dense, and without voids.

FIGURE 14: CAT scan, one year in function, multiple sagittal sections showing complete fusion of dense bone to the medial and lateral walls, as well as to the implants.

FIGURE 15: CAT scan, one year in function, computer-generated three-dimensional image (Dentascan Program) horizontal section, at the apex of the grafted site, demonstrating dense bone generation in the peripheral areas of the graft. Note lack of fusion to lateral walls whenever the Schneiderian membrane was not surgically elevated.