

SUMMARY OF ATTACHMENTS ON CASE STUDIES

CONTENTS

Pages:

1. Recent presentation to AAID MaxiCourse, Rutgers, and New York University. (page 1)
2. Most recent Antibiotics used in two University Studies for Tooth Extraction. Must follow Steps 1-3 strictly. (page 2)
3. Identify pathology of the Periodontal Ligament to be eradicated prior to Tooth Extraction if possible. Follow steps noted on page 2 to detoxify. Thereafter, remove the Lamina Dura partially in lower half of the socket lingually or palatally to the alveolar process for the 220µm sized Osteoclast cells to move into the socket and digest the graft for the Osteoblast cells to establish new bone. See drawing on page 3.
4. FOR DOCTORS INFORMATION, following Tooth Extraction (with references). Pay extra attention to Figs. 3-5 by compressing the entire plug to the level of soft tissue for making a membrane. By aggressively compacting the plug, the bone grafting crystals unite together forming a bioactive barrier to control downward migration of connective tissue.⁸⁻¹⁰ (pages 4-4a)
5. Any bone grafting particulates should not recruit the immune system (i.e., Macrophage Multinucleated Giant Cells). It has been reported that non-resorbable bone graft could affect the patient's immune system. Note references 7,16,17 on page 8a and page 5.
6. These x-rays demonstrate the thickness of Lamina Dura walls that must be removed (lingually, palatally or buccally) where the alveolar process is available to bring in (i.e., life) the bone forming cells. (page 6)
7. Abstract of study (with references) conducted at the University of South Alabama by Dr. Louis Naman to Force Mineralize and reinforce implant osteotomies with OsteoGen[®] Bioactive Resorbable Calcium Apatite crystals, having similar physicochemical and crystallographic properties to human cancellous bone, for bone bridging and better osseointegration, for immediate implant support. M. Valen presented these results to the Academy of Osseointegration.^{11,21,22} (pages 7-7a)
8. Abstract in more detail as to the understanding of the OsteoGen[®] Bone Grafting Plugs and similar materials (with references). (pages 8-8a)
9. Metronidazole liquid can be taken from an IV bag and injected in the alveolar process crestally to the Interdental Septum and socket after removal of the periodontal ligament and Lamina Dura. Additional liquid should be delivered to the socket to control pathology. (page 9)

**Biologic and Physiologic Cellular Response to Bone Grafts**

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Objectives:

- Discuss the biologic and physiologic cellular response to Dense Bone Filling Augmentation Materials that may facilitate new bone formation, versus bioactive resorbable non-ceramic crystal cluster that is easily digested by the osteoclast cells, enhanced by surgical technique after tooth extraction. These materials are also used for implant shielding surgical techniques when mixed with OG pellets to increase Bulk density mass for implant immediate support by crushing the pellets.
- Identify the comparison between "non-resorbing" Dense Filler Materials to human allograft crystal structure, and user-friendly cost effective bioactive crystal structure combined with collagen composite materials that have physical and mechanical properties similar to human bone mineral as demonstrated by synthetic calcium phosphate mineral derived from bioactive resorbable calcium apatite crystal clusters (i.e., OsteoGen® Plug).
- Demonstrate simple, predictable and cost-effective socket grafting techniques **without use of a membrane** using the OsteoGen Bone Grafting Plugs in surgical applications covering post-extraction, grafting around immediate implant placement, and filling interproximal and facial gaps.

Description:

Non-resorbing very Dense Filler Materials (i.e., ceramic HA, ceramic TCP, bovine ceramic, glass and plastics promote fibrous tissue encapsulation and **fragment** by giant cells "over decades rather than years".¹ The fragmentation of Dense Filler Materials is transported to larger organ filters in the body (i.e., lymph nodes, lungs and spleen) does compromise patient's immune systems sometime by 5-7 years.²⁻³ OsteoGen® crystals have similar physicochemical and crystallographic mineral properties to trabecular human allografts with the advantage to control connective tissue migration.⁴⁻⁶

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For Doctor's Information on Case Studies Antibiotics for Periodontal GTR and Tooth Extractions

Introduction:

When you extract a tooth due to pathology involved within the Periodontal Ligament, the Immune System (white blood cells) is called in to the socket and recruits the Alveolar Macrophage cells through the Nutrient Canals (20µm) to remove the pathology within the socket (see Tooth Drawing by Maurice Valen, page 3 attached). The Osteoclast cell is 220µm on average. In order to facilitate infiltration into the socket, the doctor must surgically remove the Lamina Dura lower half of the socket lingually or palatally. Doctors should follow Steps 1-3 below strictly for recruiting the Osteoclast cell in order to remove and digest Allografts and/or OsteoGen® Bioactive Resorbable Calcium Apatite Crystals within the Plug, both of which have the same physicochemical and crystallographic properties as cancellous allografts [Ca₅(PO₄)₃OH].

Step #1: Remove all infected and inflamed Periodontal Ligament from the walls of the Lamina Dura in its entirety and flush out completely. Do this step twice. Repeat and remove all pathology to avoid severe pain and dry socket by disintegration of the blood clot!

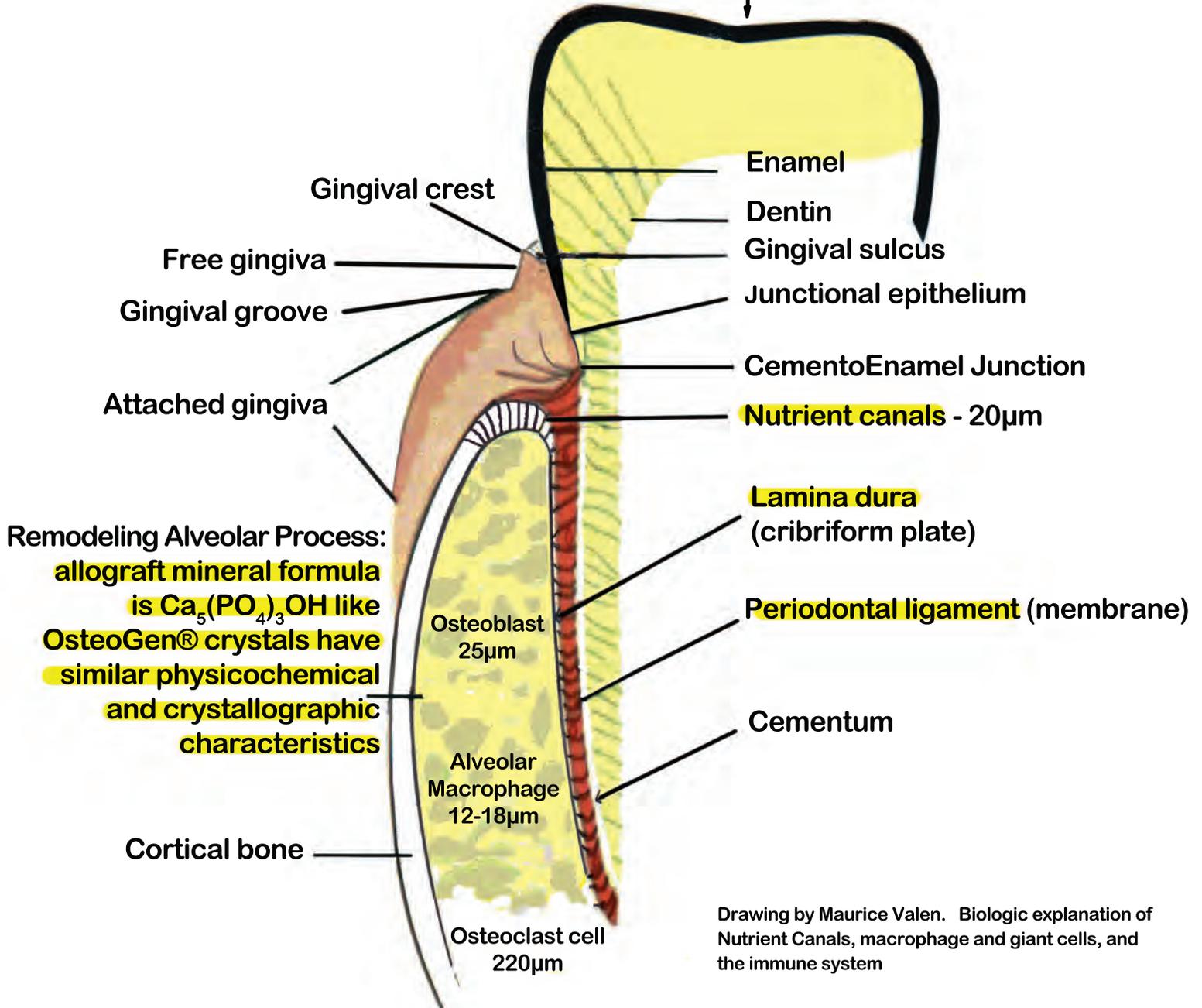
Step #2: Consider the pH of any antibiotics used as a low pH will create an acidic environment and may be detrimental to bone formation. An alternative antibiotic should be considered (i.e., Metronidazole, which has a comparatively higher pH). If infection is evident, deliver aqeuously through the 20µm nutrient canals (interdental septum and into the socket) to attack any remaining pathology (WJ Lowsche, page 4 reference 7).

Step #3: Remove the Lamina Dura lingually, palatally or buccally where trabecular bone is available to avoid dry socket and to bring in the Osteoclast cell (220 µm). Inject Metronidazole antibiotic into the socket and Interdental Septum crestally and deliver the Plug. Topical administration of antibiotics will detoxify and immediately control bacteria in the socket (see page 9).

Optional: Take a bone core biopsy following 5 month of healing. Use the Impladent Ltd black coated 3-piece Trepine with removal key to easily remove the 7.0mm bone core sample. Mail to Impladent Ltd in a formalin jar.

Occlusal Force on Molar Class II Lever
 Twice the force magnitude than bicuspid for implant selection

Valen M, Schulman A, 1990¹



Alveolar macrophage (18µm) reaction to pathology is delivered through nutrient canals (20µm) by the immune system (white blood cells) to remove the Infected Periodontal Ligament (IPL). Long term immune foreign body giant cell systemic reaction is evident due to implanted non-resorbing dense Filler Grafts next to macrophage multinucleated giant cells fragmenting the Non-Resorbable Grafts (NRG)²⁻³ (i.e., TCP, ceramic HA, glass, plastics and bovine ceramic grafts) compromising patient immune system by delivering dense grafts to lymph nodes, lungs and spleen (page 1 references 1-3). However, resorption of allografts, or OsteoGen® synthetic bioactive resorbable crystals, having similar physicochemical and crystallographic properties will be phagocytosed by alveolar macrophage cell if the IPL is not removed in its entirety. Consequently, if partial lingual, palatal or buccal Lamina Dura is not removed to the alveolar bone to bring in the 220µm Osteoclast giant cells, the process of new bone formation will not begin by the osteoclastic cutting cone.

1 Valen M and Schulman A: Establishment of an implant selection protocol for predetermined success. JOI Vol XVI No 3 166-171, 1990.

2 Sheikh Z, etal: Macrophages, Foreign Body Giant Cells and Their Response to Implantable Biomaterials. Materials. 8(9): 5671-5701,2015.

3 Miron RJ, etal: Giant cells around bone biomaterials: Osteoclasts or multi-nucleated giant cells? Acta Biomater. 46:15-28, 2016.

ALVEOLAR RIDGE PRESERVATION USING THE BIOACTIVE HYDROPHILIC OSTEOGEN® BONE GRAFTING PLUG WITHOUT A MEMBRANE FOR TOOTH EXTRACTIONS BY DENTAL SCHOOL STUDIES FOR DOCTORS INFORMATION

Doctors: Please ask your patients if they are allergic to collagen. ***Advise patients to avoid alcohol, mouthwash or chlorhexidine for two weeks as this has been shown to be toxic to fibroblasts and may retard healing and crestal bridging of soft tissue*.**

Fig. 1: Extraction and Debridement

Following anesthesia, extract tooth using standard atraumatic flapless protocol. **Thoroughly remove the granulation tissue and the entire pathologic periodontal ligament using the Implants Ltd Ultra Coarse Diamond BurSM, see photo white X, removal of all infected ligament. Debride twice and flush socket with normal saline.**¹⁻³



See Video on UCD Bur at:

<https://www.impladentltd.com/product-p/bur-kit.htm>



Fig. 2: Generate Bleeding to Establish the RAP

Using the #6 carbide bur included in the UCD kit remove the **Lamina Dura** and make lingual or palatal holes in the lower half of the socket **where trabecular bone is available** to procure medullary blood containing osteoclast cells (220µm) and osteoblasts to trigger the Regional Acceleratory Phenomenon (RAP).⁴ Profuse bleeding will be absorbed by the hydrophilic OsteoGen® Plug and will help prevent dry socket. **Do not hydrate the Plug prior to delivery.**^{5,6}



Fig. 3: Delivery and Initial Plug Compression

Antibiotics with a low pH are not conducive to rapid bone formation. Aqueous **Metronidazole** is a preferred option that is closer to physiologic normal pH. **Following removal of the Lamina Dura, inject 2-3 drops mesiodistally at each side of the ridge crest as well as into the socket to kill bacteria and inhibit alveolar macrophage activity.**⁷⁻⁹ Hold the OsteoGen® Plug with sterile tweezers, taper Plug apically and deliver into the socket. Compact the plug aggressively. The Plug should be large enough, initially with an excess of 3.0mm-5.0mm on average above occlusal plane, so that it can be compressed into and fill the entire socket to the **soft tissue superior level**. **Do not place Plug to the crestal bone height!**



Fig. 4: Final Compression: "Making a Membrane"

Plug compression is achieved by **using a Plugger Instrument to align and compact the bone grafting crystals closer together creating a bioactive membrane barrier which controls migration of connective tissue.**¹⁰⁻¹² Must use more than one Plug for multiple roots. Fill and unite the Plug roots **superiorly at the root trunk to the level of the soft tissue crest**. Leave the top of the Plug intact so it can be compressed into the socket uniformly. **No toothbrushing or waterpik and avoid alcohol, mouth wash or chlorhexidine for two weeks to yield rapid tissue healing crestally*.**



Fig. 5: Suturing; Radiolucent to Radiopaque

Passively crisscross suture over Plug, **not through the Plug**. **Do not use Resorbable sutures**. Membrane Not Required. Soft tissue should bridge across in 9-14 days*. The non-ceramic OsteoGen® crystals are a low-density graft material. Site will show radiolucent day of placement. Plug resorbs continuously in 3-5 months and longer and is replaced by host bone at a rate depending on the surgery and patient's age or metabolism. The site will become radiopaque and ready for implant placement. **OsteoGen® crystals may be used to reinforce the implant osteotomy prior to implant installation.**¹²⁻¹⁴ After implant installation, place healing screw and additional crystals crestally to prevent downward migration of epithelium & achieve primary closure.¹⁰⁻¹²



Doctor please see videos online at www.impladentltd.com/OsteoGen-Plugs-p/op.htm

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BONE FORMING CELLS : REMODELING PROCESS

1. Osteoblast bone making cells
size $25\mu\text{m} - 29\mu\text{m}$
2. Osteoclast Multinucleated giant cell
size $215\mu\text{m}$ phagocytic cell recruiting
osteoblast cell
3. Main purpose of Osteoclast is to remove
old bone or allografts $\text{Ca}_5(\text{PO}_4)_3\text{OH}$. These
cells digest materials that have the same
physicochemical and crystallographic
properties as human allograft, similar to
Bioactive OsteoGen® $\text{Ca}_5(\text{PO}_4)_3\text{OH}$, a
resorbable calcium apatite crystal.

BONE CELL IMMUNE SYSTEM: (Cleaning Crew)

4. Macrophage size $18\mu\text{m}-21\mu\text{m}$ removes
diseased bone and allografts at tooth extraction
site having the formula of $\text{Ca}_5(\text{PO}_4)_3\text{OH}$
5. Macrophage Multinucleated giant cells
(MMGC) have capacity to Fragment Filler
Dense Grafts: Ceramic HA, TCP, Plastics,
Bovine Ceramics.
6. **MMGC cells do not have capacity to**
consume or digest Dense Filler Grafts, or
recruit the osteoblast to make bone. MMGC
will Fragment Dense Filler materials and
transport to lymph nodes, lungs and spleen,
and patient could lose their immune system.



ABSTRACT

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Abstract Details

CURRENT CATEGORY: Clinical

PRESENTATION TYPE: Oral: Given at Academy of Osseointegration in San Diego, February 2016

Abstract

Dental Implant Orthopedics Basic Science Primer with Bone Grafting Techniques for Implant Success

Valen, Maurice; Naman, Louis J.; Hughes, Richard; Minichetti, John; Locante, William; Walton, Charles; Hall, Leo

ABSTRACT BODY:

Introduction: To predetermine bone to implant success of 25 patients, we had to (1) register applied muscular force at designated implant site using transducer instrumentation, (2) approximate bone quality by Cone Beam values “equated” to Hounsfield (HU)¹ and, (3) select implants with sufficient Load Bearing Areas (LBA) to establish applied force and resisting force for implant equilibrium. Relationship between applied and resisting forces (metal-to-bone support) dictates success because bone works best in compression and these forces should be equal for long term implant function.²⁻⁶

Method: CT scans can be off by 15%. If implant receptor sites are deficient, bone graft is often required to fortify sites with material of similar chemical-mechanical properties less than trabecular bone. The aim is to increase implant support values without abuse to bone at implant interface. To achieve resorption, the graft should have mechanical strength less than human trabecular bone and increase foundation of deficient sites. Crystal technology of bioactive resorbable calcium apatite crystals (non-ceramic) to force mineralize implant osteotomy three- dimensionally using a surgical motor with 3-D dilators to accelerate osseointegration.⁵⁻⁶ Osteotomy diagnosis is accomplished by using surgical motor with sensor control to stop at given bone density resistance by Ncm to HU to surgically convert poor bone quality (-D4) to +D3 or +D2.

Results: Implant placement was accomplished, for the last 10 years, at torque values of 42-45 Ncm for D3 bone, equivalent to 375-475 HU and 48-51 Ncm or 575-675 HU for D2 bone resistance. Bioactive grafting crystals are used to establish bone bridging for cells to move in space achieving osseointegration.⁷⁻¹⁶

Conclusion: Preventing connective tissue migration is beneficial for implant placement because of bioactive resorbable calcium apatite crystal having physicochemical crystallographic characteristics similar to human trabecular bone crystals.⁷⁻¹⁶ Evidence-based results using 3-D Force Mineralization Techniques (FMT) and science of Electro-Streaming Potentials to achieve predictable osseointegration and greater bone volume within physiologic limits.¹⁶⁻¹⁷ Using crystal properties of resorbable OsteoGen[®] similar to human bone^{8-9,11-13} unlike ceramic, glass, plastic or bovine ceramic “filler materials which resorb over decades rather than years” encumbered by fibrous tissue and systemic complications.¹⁷⁻²²

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ABSTRACT

Predictable and Cost-Effective Bone Graft Composites: From Socket Preservation to Advanced Surgical Concepts in Bone Regeneration for Implant Placement

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This course covers a spectrum of pliable preformed shapes used for bone grafting procedures with implant placement, from simple and cost effective socket grafting to more advanced clinical concepts in bone regeneration. Surgical techniques and novel biomaterials will be discussed using OsteoGen[®] synthetic resorbable calcium phosphate bone graft combined with collagen as a biomaterial with crystals having similar mechanical properties to human cancellous bone.⁶⁻¹¹ Speakers will review state-of-the-art clinical guidelines, surgical techniques for alveolar ridge preservation as well as grafting around immediately placed implants in extensive clinical situations. The science and biological basis of growth factor utilization in bone and soft tissue applications will be reviewed using L-PRF technology combined with the OsteoGen[®] Plug. The integration of these principles to generate biologically modified, yet cost effective, biomaterials will be reviewed.

- Demonstrate simple, predictable and cost effective socket grafting techniques **without the use of a membrane** using the OsteoGen[®] Bone Grafting PlugsSM in surgical applications covering post-extraction, grafting around immediate implant placement and filling interproximal and facial gaps.
- Learn the crystal structure and use of cost effective bone graft/collagen composite materials that have physicochemical and crystallographic characteristics similar to human bone mineral derived from bioactive resorbable calcium apatite crystal clusters.
- Discuss the biologic and physiologic cellular response to bone grafts for enhanced bone regeneration.

Conclusion: Very dense filler materials (i.e., ceramic HA, TCP, bovine ceramic, glass and plastics¹²⁻¹⁵) promote fibrous tissue encapsulation and fragment by giant cells over decades rather than years.¹⁶⁻¹⁷ The fragmentation of filler materials is transported to larger organ filters in the body (i.e., lymph nodes, lungs and spleen) does compromise patients immune systems.¹⁶⁻¹⁷ OsteoGen[®] crystals have similar physicochemical and crystallographic properties to trabecular human allografts with the advantage to control connective tissue migration. (Spivak 1990, Ricci 1992, Valen 2002)

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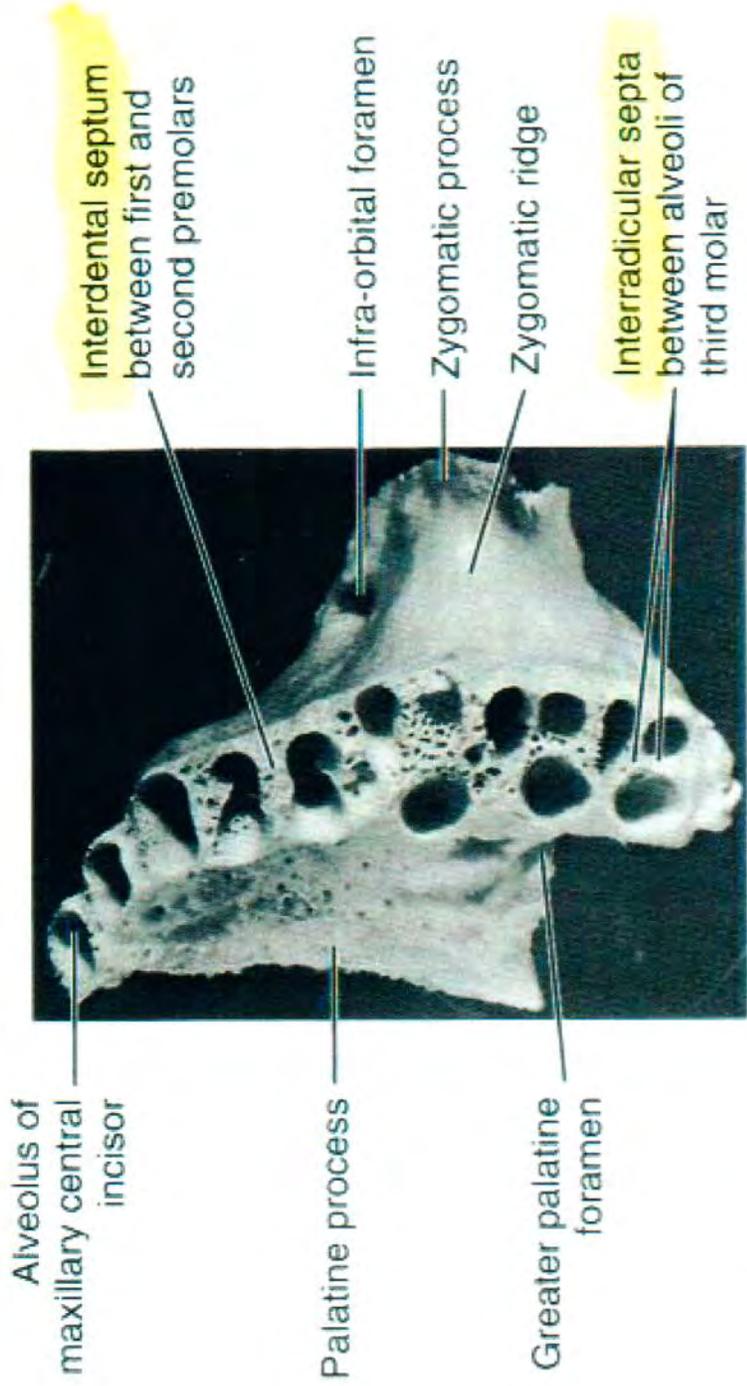
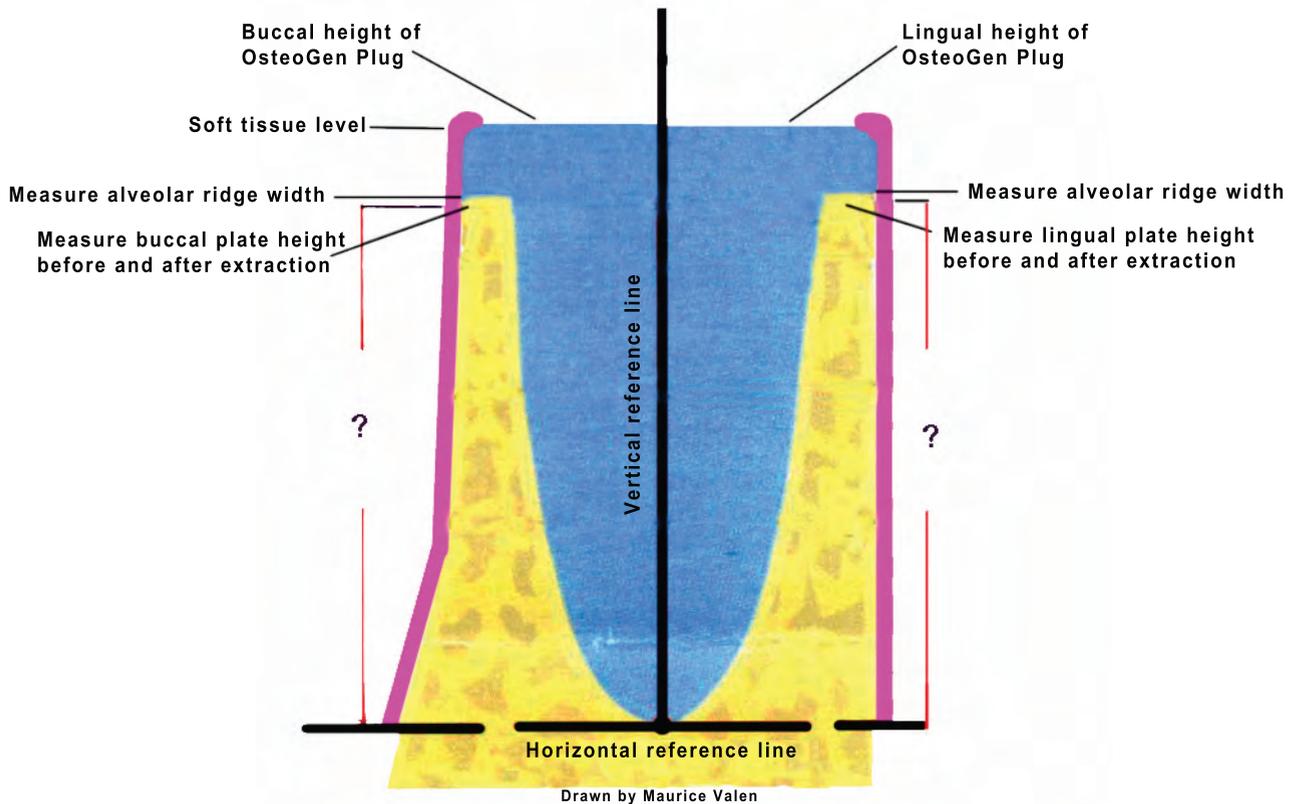


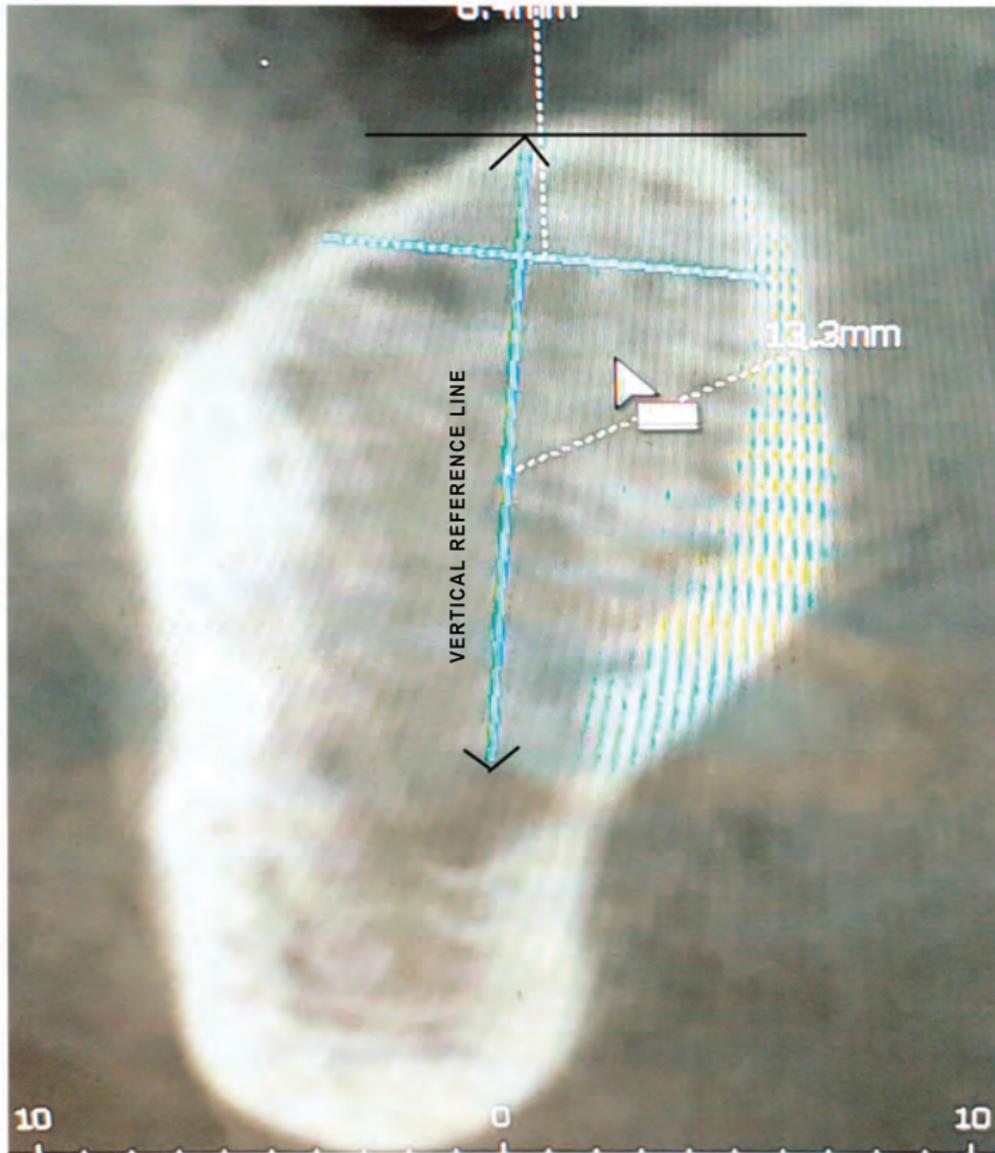
FIGURE 14-8 View of inferior surface of the maxilla showing alveolar process and alveoli.

USING A CBCT, TAKE THE FOLLOWING MEASUREMENTS:

**Measure vertical buccal and lingual plate height before and after tooth extraction
Measure buccolingual crestal width**



**PROVIDE THIS INFORMATION TO THE SPONSOR ON THE DAY OF SURGERY AND
AT 5 MONTHS POST-OP FOR PERIODONTAL DEPARTMENT TO PUBLISH IN A JOURNAL**



CBCT measurements from crest of bone to the alveolar canal

Summary of Allograft Core Samples

Author	Allograft	% vital bone	% residual graft	% connective tissue/other
Froum et al (2002) cores at 6-8 months	Demineralized	35	14	51
Beck (2010) cores at 3 months	Mineralized	46	14	40
Beck (2010) cores at 6 months	Mineralized	45	14	41
Wood et al (2012) cores at 4-5 months	Mineralized	25	25	50
	Demineralized	38	9	53
Toloue et al (2012) cores at 3 months	Mineralized	17	21	62