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RIDGE PRESERVATION COMPARING THE CLINICAL AND HISTOLOGIC HEALING OF A MINERALIZED PARTICULATE ALLOGRAFT WITH A **NONPOROUS PTFE MEMBRANE** VS. **MINERALIZED PARTICULATE XENOGRAFT WITH A COLLAGEN PLUG MEMBRANE**

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By

Jason A. Witonsky DMD, University of Pennsylvania, 2006

A Thesis Submitted to the Faculty of the Graduate School of the University of Louisville in Partial Fulfillment of the Requirements for the Degree of

Master of Science

Program in Oral Biology School of Dentistry University of Louisville Louisville, Kentucky

August 2009

RIDGE PRESERVATION COMPARING THE CLINICAL AND HISTOLOGIC HEALING OF A MINERALIZED PARTICULATE ALLOGRAFT WITH A NONPOROUS PTFE MEMBRANE VS. MINERALIZED PARTICULATE XENOGRAFT WITH A COLLAGEN PLUG MEMBRANE

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A Thesis Approved on

August 7, 2009

By the following Thesis Committee:

Thesis Director

II

DEDICATION

This manuscript is dedicated to my parents for their love and support and to the pursuit of science. The love and support from my parents has been invaluable. It has made me a humble, hard working, caring, and skillful healthcare provider. Science has the ability to enlighten humanity; therefore my efforts go towards its pursuit.

ACKNOWLEDGEMENTS

I would like to express my sincere gratitude to the following individuals:

- Dr. Henry Greenwell, Program Director of Graduate Periodontics, for his invaluable guidance and mentoring in my training as a periodontist, his help in the preparation of this thesis and for the lifelong friend I have acquired.
- Dr. Margaret Hill, Assistant Program Director, for her inspiration and commitment to excellence and her caring encouragement of all the residents.
- Dr. Brian S. Shumway, Assistant Professor, thank you very much for all of your help. I appreciate all of your input into my thesis.

ABSTRACT

RIDGE PRESERVATION COMPARING THE CLINICAL AND HISTOLOGIC HEALING OF A MINERALIZED PARTICULATE ALLOGRAFT WITH A NONPOROUS PTFE MEMBRANE VS. MINERALIZED PARTICULATE XENOGRAFT WITH A COLLAGEN PLUG MEMBRANE

Jason Witonsky, DMD

August 7th, 2009

Aim. To compare two techniques of ridge preservation using a cancellous mineralized particulate xenograft plus a collagen plug to a cortical mineralized particulate allograft plus a PTFE membrane using ridge dimension data to assess the outcome.

Methods. Twenty-eight total patients were seen in the Graduate Periodontics Clinic at the University of Louisville School of Dentistry. Fourteen positive controls received a mineralized particulate xenograft (0.25 to 1.00 mm) covered by a collagen plug using a full-thickness flap technique (Plug group). Fourteen test patients received an intrasocket mineralized cortical particulate allograft (500 to 800 μ m) covered with a nonporous PTFE membrane also using a full thickness flap technique (PTFE group). Following tooth extraction, horizontal ridge dimensions were measured with a digital caliper and vertical ridge dimensions were measured from a stent. Each site was re-entered for implant placement at about 4 months. Prior to implant placement, a 2.7 X 6 mm trephine

core was obtained and preserved in formalin for histologic analysis.

Results. The mean horizontal ridge width at the crest of the Plug group decreased from 8.6 \pm 1.0 mm to 7.3 \pm 1.0 mm for a mean loss of -1.3 \pm 0.9 mm (p < 0.05) while the PTFE group decreased from 7.9 \pm 1.5 mm to 6.8 \pm 1.4 mm for a mean loss of -1.1 \pm 1.1 mm ($p < 0.05$). There were no statistically significance differences between the two groups ($p > 0.05$). The mean mid-buccal vertical change for the Plug group was a loss of -0.1 ± 1.6 mm (p > 0.05) vs. a gain of 0.4 \pm 2.1 mm (p > 0.05) for the PTFE group. There were no statistically significant differences between groups for vertical change ($p >$ 0.05). The Plug group demonstrated $28 \pm 20\%$ vital bone, $37 \pm 16\%$ non-vital bone, and 35 \pm 13% trabecular space. The PFTE group demonstrated 35 \pm 21% vital bone, 31 \pm 22% non-vital bone, and 34 \pm 10% trabecular space. There were no statistically significant differences between groups ($p > 0.05$).

Conclusions. Mean crestal ridge width was preserved for both the Plug and PTFE groups and there were no statistically significant differences between groups ($p > 0.05$). There was a trend toward greater loss of mean mid-buccal ridge height for the Plug group, although there were no statistically significant differences between groups ($p > 0.05$). The mean CEJ to osseous crest distance showed only a minimal loss of 0.7 mm or less, with no statistically significant differences between groups ($p > 0.05$).

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CHAPTER I

LITERATURE REVIEW

Tooth extraction has become a significant part of periodontal practice. The demand for dental implants as a tooth replacement requires clinicians to perform ridge preservation at the time of extraction to maintain post-extraction ridge width. This ensures a better site for future implant placement that satisfies both functional and esthetic requirements. Ridge preservation is an alternative to immediate implant placement when requirements of primary stability, adequate ridge dimensions or esthetics cannot be achieved. It is important to understand the events following tooth extraction that have been studied in both animals and humans in order to appreciate the most likely effects on ridge dimensions with or without a ridge preservation procedure.

Animal Extraction Socket Healing Sequence

The majority of the information about animal socket healing has been studied using the canine model. The earliest studies were completed in animals in the 1930's. Clafin (1936) provided data on the histologic healing of extraction sockets up to 31 days in dogs (Table 1). According to Clafin (1936), healing began with clot formation at day 1, followed by infiltration with osteoclasts at day 3, then bone formation around 5-7 days.

Epithelialization was complete over the clot around 7-9 days and complete socket fill occurred by 31 days. Despite complete socket fill, osteoclasts were still present, indicating that the healing was not complete at 31 days. Cardaropoli et al. (2003) extended the histologic analysis of the healing process of extraction sockets in beagle dogs to 180 days (Table 2). Both studies showed that the initial process after extraction was the formation of a blood clot at day 1. Subsequent to that, neovascularization played a significant role up to 14 days when new bone was formed along the socket walls. By day 30, in accord with Clafin, the socket was completely filled with bone. According to Cardaropoli et al. (2003), the bone at 30 days was immature. It was not until day 90 that this woven or immature bone had remodeled to become lamellar, mature bone. By day 180, the lamellar bone had undergone further remodeling and showed a slight decrease in mineralization due to the replacement of lamellar bone with bone marrow. Araujo et al. (2005a) examined histologic socket healing in the dog model using 12 sockets in 12 mongrel dogs over a period of 8 weeks (Table 3). At 1 week, the central portion of the socket was occupied by coagulum. At the apical portion, islands of newly formed woven bone were noted adjacent to the bundle bone. By 2 weeks, large amounts of newly formed bone were found in the apical and lateral portion of the socket. The surface of the woven bone was lined with densely packed osteoblasts and included a primitive bone marrow. By week 4, the crestal bone, which was completely composed of bundle bone, was lost. Apical to the crestal region, a multitude of osteoclasts were observed on the outer surfaces of the buccal and lingual walls. By week 8, the lingual wall had become wider than the buccal wall and was positioned 2 mm coronally to the buccal wall. A zone of mineralized tissue, which consisted of a mixture of woven and lamellar bone, had formed between the buccal and lingual walls. This bridge of mineralized tissue traveled in an oblique direction. Two major findings from this study were: 1) the bundle bone began to disappear as early as 2 weeks post-extraction, and 2) the buccal wall undergoes a significantly greater amount of resorption than the lingual wall.

Table 1

Animal Extraction Socket Healing 31 Days (Clafin 1936)

Table 2

Animal Extraction Socket Healing 180 Days (Cardaropoli et al. 2003)

Table 3

Animal Extraction Socket Healing 56 Days (Araujo et al. 2005a)

Time	Event
Day 7 $(1$ week)	- internal portion of the socket occupied by coagulum - apical portion showed islands of newly formed woven bone adjacent to the bundle bone.
Day 14 (2 weeks)	- apical & lateral portions showed large amounts of newly formed woven bone - surface of the woven bone was lined with densely packed osteoblasts - primitive bone marrow.
Day 28 $(4$ weeks)	- at the crestal region, all bundle bone had been lost - crestal lamellar bone replaced with woven bone. - apical to the crestal region, a multitude of osteoclasts were observed on the outer surfaces of the buccal and lingual walls.
Day 56 $(8$ weeks)	- lingual wall wider than buccal wall - lingual wall positioned 2 mm coronal to buccal wall - zone of mineralized tissue which consist of a mixture of woven and lamellar bone had formed between the buccal and lingual walls traveling in an oblique direction.

Araujo et al. (2005b) also examined socket healing with placement of an immediate implant and Berglundh et al. (1994) studied the vascular supply around Branemark implants in beagle dogs. It was observed that the blood vessels of the periimplant mucosa were terminal branches of larger vessels from the periosteum at the implant site. The peri-implant supracrestal connective tissue, in comparison to a tooth, was almost devoid of vascular supply, which could potentially influence healing. Carmagnola et al. (2000) examined the histologic healing around implants placed in sites previously grafted with mineralized cortical bovine xenograft (Bio-Oss). They created 16 surgical defects in 4 beagle dogs. Osseointegration failed to occur at the implant surfaces and a well-defined connective tissue capsule was present between implant surfaces. A deep vertical bone defect was frequently present along the lingual surface of the implant.

Botticelli et al. (2004) examined the effects of three different surgically created defect configurations on bone healing around implants. They found that the 4-wall defects fully resolved following implant placement. Two wall defects with the buccal and lingual plates intentionally removed showed incomplete healing. Botticelli et al. (2005), in a follow-up study, examined the effects of implant surface, implant position and the presence of combined horizontal and vertical residual peri-implant defects on osseointegration in Labrador dogs. After 4 months of healing, regardless of whether the implant was placed in a submerged or nonsubmerged position, a substantial amount of bone fill and a high degree of osseointegration was noted around roughened implants compared to machined implants. This result suggests that implant surface characteristics played an important role in the amount of hard tissue fill and level of osseointegration. Araujo et al. (2005b) studied the effects of immediate implant placement on the dimensional alterations of the alveolar ridge in beagle dogs. They compared sites that received an immediate implant to contralateral sites that received extraction alone over a period of 3 months. Results revealed that marked dimensional alterations, including decrease both in height and width of the ridge, had occurred in the extraction alone sites. The placement of an immediate implant decreased but did not prevent dimensional changes that occurred in the ridge. After 3 months of healing results were similar for both groups.

Human Extraction Socket Healing Sequence

Various authors studied the extraction socket healing sequence in humans. Amler (1960), examined histologically a total of 75 human extraction sockets over a period of 100 days. In a study of 12 patients requiring extractions of all remaining maxillary teeth, Boyne (1966) examined the histological healing of one of the maxillary first premolar sockets over 23 days. Evian (1982) examined the histologic healing in 10 patients over a period of 16 weeks. Biopsies were taken at 4, 6, 8, 10, 12, and 16 weeks post-extraction. Taken together, these studies showed that the human healing sequence followed a similar pattern to the dog model (Table 4).

Table 4

Human Extraction Socket Healing over 100 Days

The first event in the healing sequence of both human and dogs was the formation of a blood clot at day 1 (Clafin 1936, Amler 1960). The first evidence of new bone formation

in dogs was seen around day 5 and along the lateral aspect of the socket by day 11 (Clafin 1936). In humans, the first evidence of new bone was not detected until day 7-10. Complete socket fill was observed around day 30 in dogs. This is in contrast to human studies where Boyne (1966) reported that only 1/3 of the socket was filled by day 14, and Amler noted that only 2/3 of the socket was filled at day 38. Mature, lamellar bone was seen in dogs at day 90 (Cardaropoli et al. 2003), and this was not evident until day 100 in humans (Amler 1960). Table 5 compares the socket healing sequence for the dog and human models.

Table 5

Events **In** Extraction Socket Healing

Alveolar Ridge Resorption Following Tooth Extraction

Loss of alveolar bone volume, both width and height, after tooth extraction is a inevitable outcome. The greatest amount of bone loss occurs within the first 2 years after tooth removal (Ashman 2000). Loss of alveolar ridge width and height can complicate placement of an endosseous dental implant since there must be adequate bone to completely surround the dental implant. Whether the residual ridge position is centered

compared to the original edentulous ridge, or it has shifted toward the lingual, is an important consideration. Ridge position can have a significant effect on implant placement, esthetics, and the subsequent occlusal relationship of the restored implant. Previous studies have reported that most ridge resorption occurs on the buccal, resulting in a shift of the center of the ridge toward the palatal/lingual, (Lekovic et al. 1997, Lekovic et al. 1998, Iasella et al. 2003). Pietrokovski and Massier (1967) evaluated 149 dental casts with one tooth missing. They found that the buccal surface of both the maxilla and the mandible resorb more than the lingual/palatal sides with a distinct shift of the center of the ridge to the palatal/lingual. The amount of facial resorption varied considerably between individual sites. Schropp et al. (2003) evaluated study casts from 46 patients with a single premolar or molar extraction over a 12-month period and found that most (2/3) resorption happened within the first 3 months. Yilmaz et al. (1998) examined study casts from 5 patients (10 sites) with a single maxillary incisor extraction that was followed for a 12-month period and noted a 17% decrease in ridge width. Barone et al. (2008) evaluated 40 patients (40 sites) in a non-molar extraction study that was followed for 7 months. He noted a decrease of 41.7% in ridge width. The amount of buccal-lingual ridge resorption after tooth extraction has been reported as 17-63% with the ridge height decreasing by 1 mm, (Lekovic et al. 1997, Lekovic et al. 1998, Yilmaz et al. 1998, Camargo et al. 2000, Schropp et al. 2003, lasella et al. 2003, Barone et al. 2008). Data from these studies indicated that change in ridge width following tooth extraction varied substantially. Table 6 consists of a list of studies that examined the mean change in the horizontal and vertical ridge dimensions following tooth extraction alone. These resorptive changes in ridge dimension may preclude future implant

placement, or require additional surgical treatment to allow placement of functional, esthetic implants if ridge preservation is not performed at the time of extraction. Table 7 reports the ridge dimensions for the studies and percent change in ridge width.

Table 6

Extraction Alone Studies Showing Change Alone

 $* =$ measured from study casts

Table 7

Reentry Mean Mean Fin Mean Horiz % change Study Time Initial Horiz Change

(months) Horiz Horiz Change Lekovic et al. 1997 6 7.0 2.6 -4.4 -63 Lekovic et al. 1998 6 7.5 2.9 4.6 -61 Yilmaz et al. $1998*$ 12 1 4.7 3.9 -0.8 1 -17 Camargo et al. 2000 $\begin{array}{|c|c|c|c|c|c|c|c|c|} \hline \end{array}$ 6 $\begin{array}{|c|c|c|c|c|c|c|c|} \hline \end{array}$ 4.4 $\begin{array}{|c|c|c|c|c|c|c|c|} \hline \end{array}$ -3.1 $\begin{array}{|c|c|c|c|c|c|c|c|c|} \hline \end{array}$ -41 Iasella et al. 2002 $\begin{array}{|c|c|c|c|c|c|} \hline 4-6 & 9.1 & 6.4 & -2.6 & -29 \ \hline \end{array}$ Schropp et al. $12 \t 12.0 \t 5.9 \t -6.1 \t -51$ Barone et al. 2008 $\begin{array}{|c|c|c|c|c|c|c|c|c|} \hline 7 & 10.8 & 6.3 & -4.5 & -42 \ \hline \end{array}$ Mean 7.6 ± 3.2 8.4 ± 2.5 4.6 ± 1.6 -3.7 ± 1.7 -43 ± 17

Extraction Alone Studies Showing Ridge Dimensions

Clinical Studies of Ridge Preservation

With the emergence of dental implants, ridge preservation has become a frequent part of periodontal plastic and reconstructive surgery. The goal of ridge preservation is minimizing bone loss to preserve the maximum final, healed ridge dimensions. Osseous ridge preservation is done using a hard tissue graft. Without this procedure there may be inadequate ridge width to allow implant placement. Ashman (2000) noted that when an extraction takes place and ridge preservation is not utilized the site of extraction could lose 40% to 60% of bone height and width within 2 to 3 years and subsequent loss of 0.25% to 0.5% annually. Iasella (2003) reported as much as 4 mm loss of ridge width in extraction alone sites within 6 months. Using an atraumatic tooth extraction technique preserves osseous walls thereby improving the chances of osseous graft success. Garg (2001) discussed 5 steps he considered necessary for an atraumatic extraction: 1) do not

reflect the interdental papilla, especially in the esthetic zone; 2) focus on the actual process of tooth removal; 3) use elevators and forceps properly to reduce bony involvement and preserve bone contours; 4) section the tooth to help prevent bone loss; and 5) remove any soft tissue fragments or pathology. Horowitz (2005) added that use of a periotome is an important adjunct to atraumatic extractions. He says it is used to sever the periodontal ligament fibers, which enables the extraction to be accomplished with significantly less trauma. The greater the number of bony walls present following extraction the more likely the osseous graft will be successful. According to Garg (2001), the bone defect can be categorized into one of the following categories: fivewalled, four-walled, three-walled, two-walled, or one-walled defects. Comparison studies have shown that intrasocket ridge preservation prevents most, but not all, ridge resorption. Several ridge preservation studies have used barrier membranes to attempt to improve quality and quantity of bone fill in extraction sites. Both resorbable and nonresorbable barrier membranes have been used; some studies used membranes alone, others used membranes in conjunction with intrasocket grafting materials. Lekovic et al. (1997) compared extraction alone to use of a non-resorbable barrier membrane alone (Gore-Tex®) and Lekovic et al. (1998) compared extraction alone to use of a resorbable barrier membrane alone (Resolut®). In both studies, the teeth included were anterior teeth or premolars. The teeth were atraumatically extracted, the membrane was placed and primary closure was obtained. Reentry was performed 6-months post-extraction. The results showed that both the non-resorbable (Gore-Tex®) and resorbable (Resolut®) barrier membranes provided comparable results. There was mean vertical resorption of 0.35 mm and a mean horizontal resorption of 1.53 mm (20%). Results from Lekovic et

al. (1997, 1998) reveal that the mean horizontal bone loss in the non-resorbable group (Gore-Tex®) was 1.73 mm, which was greater than the mean of 1.32 mm found in the resorbable membrane (Resolut®) group. The extraction alone control group lost a mean of 4.5 mm. The non-resorbable membrane sites had a mean of 3.70 mm (2.5-times) reduced horizontal loss than sites treated with extraction alone while the resorbable membrane sites had a mean of 3.27 mm (3.5-times) reduced horizontal loss. These two studies show that there is not much difference between use of a resorbable vs. a nonresorbable membrane for ridge preservation. Membrane use did, however, greatly decrease the amount of horizontal and vertical bone resorption when compared to extraction alone.

Yilmaz et al. (1998), using study models in a 16-patient, 27-socket study compared the use of bioactive glass (PerioGlas®) in fresh maxillary incisor extraction sites to extraction alone. Sites treated with bioactive glass (PerioGlas®) had a slight gain (0.2 mm) in ridge width, and minimal (0.1 mm) loss of ridge height over a period of 12 months. This was in contrast to the extraction alone group, which demonstrated a much greater loss of ridge width (0.75 mm), and ridge height (1.35 mm).

Camargo et al. (2000), in a 32 nonmolar site ridge preservation study with 6 month re-entry examined the use of bioactive glass (BioGran®) and calcium sulfate (Capset®) to extraction alone. They reported that the mixture of bioactive glass and calcium sulfate resulted in a mean loss of ridge width and height of 3.48 mm and 0.4 mm, respectively. In contrast, the extraction alone group showed slightly less loss in ridge width (3.06 mm), and a greater loss in ridge height (1.0 mm) over 6 months. Iasella et al. (2003) in a 4 to 6-month reentry study used 24 nonmolar sites and compared the use of freeze-dried bone allograft (FDBA) with a membrane to extraction alone. After four to six months of healing, the sites grafted with FDBA gained 1.3 mm in ridge height and lost only 1.2 mm in ridge width, in comparison to the extraction alone group, which had twice the amount of ridge width loss (2.6 mm), and 0.9 mm ridge height loss.

Barone et al. (2008), examined corticocancellous porcine bone and a collagen membrane to extraction alone in a 40 nonmolar ridge preservation study with a 7 month re-entry. He reported that the corticocancellous porcine bone and collagen membrane group had a mean loss of ridge width and height of 2.5 mm and 0.7 mm, respectively. For the extraction alone group, he reported a mean loss of ridge width and height of 4.3 mm and 3.6 mm, respectively. In a 10 patient case series, Cardaropoli (2008) also studied corticocancellous porcine bone and a collagen membrane over 4 months. He reported a mean loss of 1.8 mm in ridge width after 4 months.

In addition to the extraction alone comparison studies, others have evaluated the effects of various graft materials used to preserve ridge dimensions. Nemcovsky and Serfaty (1996), in a 12-month, 23-patient, 23-socket study using non-resorbable hydroxyapatite (RA) crystals, showed a loss of ridge width of 0.6 mm and a loss of ridge height of 1.4 mm over 1 year. Simon et al. (2000) in a 4-month reentry study using particulate demineralized freeze-dried bone allograft (DFDBA) as an intrasocket and a buccal overlay graft along with a barrier membrane (Resolut XT®), reported an initial ridge width of 6.2 ± 0.2 mm increasing to 7.3 ± 0.2 mm for a gain of 1.1 mm. Zubillaga et al. (2003), in a IO-patient, ll-socket study compared the use of DFDBA (Regenafil®) and a resorbable barrier membrane (Resolut®) with or without fixation at four months. They reported that the mean change in ridge dimensions was a loss of 1.8 mm width, and

a gain of 1 mm height. Vance et al. (2004), in a 4-month nonmolar reentry study using 24 extraction sockets compared the use of anorganic bovine bone matrix (BioOss®) with a membrane to DFDBA plus mixture of calcium sulfate and carboxymethyl cellulose (CalMatrix®). They demonstrated that both groups had a mean loss of 0.5 mm ridge width. The BioOss® group showed a gain in mean ridge height of 0.7 mm, while the CalMatrix® group showed a mean loss of 0.3 mm. Adams et al. (2005) compared two different ridge preservation techniques in nonmolar sites in a 4 month re-entry study. An intrasocket FDBA graft alone was compared to an intrasocket plus a buccal overlay (extrasocket) FDBA graft. The intrasocket alone group had a mean ridge width loss of 2 mm and no change in ridge height. In contrast, the overlay group showed a mean ridge width loss of 1.4 mm and a gain of 2.2 mm of ridge height. Brkovic et al. (2008) in a single case report evaluated an alveolar preservation technique involving placement of a cone of beta-tri-calcium phosphate (TCP) combined with type I collagen without the use of a barrier or flap. Nine months after tooth extraction, they reported no reduction in ridge height and no change in ridge width (12 mm). Neiva et al. (2008) in a 24 patient study over 4 months compared an anorganic bovine-derived hydroxyapatite matrix combined with a synthetic P-15 (Putty PIS) and a bioabsorbable collagen wound dressing to a bioabsorbable wound dressing alone. Neiva reported a loss of 1.31 mm in ridge width and a gain of 0.15 mm in ridge height for the Putty PIS group. For the bioabsorbable collagen wound dressing alone, a loss of 1.43 mm for ridge width and a loss of 0.56 mm in ridge height was reported (Table 8,9).

Polytetraflouroethylene Technique Studies

Traditionally, porous non-resorbable membranes such as the expanded polytetrafluorethylene (ePTFE) membrane and resorbable membranes had complications during guided bone regeneration (GBR) procedures. The ePTFE membrane had high rates of infection due to membrane exposure and its porous nature (Bartee 2001). Most resorbable membranes are type I collagen or type I-III collagen which have necessitated primary closure to prevent exposure to oral environment. Infections do not occur as frequently with resorbable membranes as with the ePTFE membrane; however, degradation of the membrane does occur with membrane exposure. To counter the problems of the ePTFE membrane and resorbable membranes, Bartee (2001) developed a dense polytetrafluouroethylene (PTFE) membrane.

According to Bartee (2001), the dense PTFE membrane offers 4 primary advantages over the ePTFE and resorbable membranes in extraction site reconstruction: 1) Due to the low porosity (0.3) micrometers), the dense membrane resists the incorporation of bacteria into its structure and can be left exposed in the mouth with a low risk of infection and subsequent graft loss. Exposure of the membrane does not compromise the underlying bone graft. 2) The ability of the membrane to remain exposed also reduces the need for the development of large flaps and vertical incisions to achieve primary closure. The nonresorbable polymer prevents premature degradation associated with exposure of resorbable membranes. 3) Conservation of soft tissue architecture is achieved since primary closure is not required. There is no loss of

vestibular depth, and the attached mucosa and interdental papilla can be preserved by using careful surgical technique. 4) The membrane does not allow ingrowth of the surrounding connective tissues, and removal is accomplished without anesthesia, surgery, or trauma to the adjacent tissues.

The procedure is indicated following the extraction of single or multiple teeth. Active infection is the only absolute contraindication. Bartee (2001) describes the PIFE ridge preservation technique as follows: 1) The first rule of ridge preservation is nontraumatic extraction. 2) Following root removal, sharp curettage should be carried out to remove remnants of periodontal ligament as well as any soft tissues such as periradicular cysts. Theses tissues may harbor pathogenic bacteria that may lead to postoperative complications. 3) Perforation of the socket cortical plate (decortication) is optional but may be helpful in establishing blood supply to the graft from the adjacent bone. 4) Using a periosteal elevator or syringe, the graft material is delivered to the extraction site and packed gently to the apex of the site. Overpacking is to be avoided because this only hinders revascularization of the site. 5) A section of membrane material is then cut to fit over the site extending 3 to 4 mm beyond the socket margins onto sound host bone. The membrane should be trimmed to maintain a 1.0 mm margin from adjacent tooth root to facilitate reattachment of the papilla to the interdental bone. The membrane should fit over the site and under the mucoperiosteal flap without wrinkling or buckling. 6) Suturing is accomplished with interrupted sutures at the interdental papillae and a single or horizontal mattress suture across the socket opening. The recommended suture material is 3-0 polyglycolide (Vicryl, Ethicon Inc, Somerville, NJ) or PfFE Monofilament. Excessive tension on the flaps should be avoided to

maximize blood flow within the flap and avoid necrosis of the flap margins. 7) Thorough irrigation of the site to remove all remaining graft particles is done. 8) Postoperatively, the patient should be observed at 1 week. At 2 weeks, sutures should be removed and the membrane cleaned if there is significant bacterial accumulation. 9) Membrane removal is done at either 3 or 4 weeks postoperatively, depending on the size of the defect and the condition of the walls. Removal is accomplished by grasping the membrane with forceps and gently removing it from the tissue bed. No anesthesia is required for this procedure, however topical anesthetic may be used. Upon removal, the graft material can usually be visualized, well consolidated in the osteoid matrix underlying the membrane. Re-epithelialization of the underlying tissue will occur over the next 7 to 10 days.

In a 4 patient case series, Bartee (1998) describes the histologic findings of PTFE ridge preservation and implant guided tissue regeneration (GTR). Two patients had ridge preservation alone and two patients had immediate implants with grafting. The patients received a graft paste consisting of 60% human freeze-dried demineralized bone (FDDB) granules (Dembone 300-500 micrometers and low-density, and 40% resorbable calcium phosphate (OsteoGraft/LD 300 OsteoGen). After adequate reflection of the mucoperiosteal flaps, the membrane was trimmed with sharp scissors and placed over the extraction site, extending 3 to 5 mm beyond the defect. Tissue samples were demineralized and stained with hematoxylin and eosin. New bone formation was clearly evident in all tissue sections. No areas of inflammatory infiltrate were noted. The bone graft particles were observed in various states of dissolution, resorption, or remodeling.

The bone was mature, dense lamellar bone. Overall, the regenerated tissue was well vascularized and there were no areas of fibrosis or chronic inflammation.

Horowitz (2005) reviewed the nonexpanded polytetrafluoroethylene (TefGen-FD) barrier in 2 case reports. The patients in this study had sites that were treated simply by protecting a blood clot with a removable, nonexpanded PTFE barrier over the extraction socket. This investigation evaluated the early (3 to 6 month range) healing and ingrowth of vital bone into an extraction socket and the maturation of overlying soft tissue. "To help promote GBR and protection of the healing socket while maintaining stability of the barrier, it is placed directly onto the outersurface of the bone and overlaps the facial and lingual walls of the socket". Proximal contouring of the material is performed to leave 1 mm of bone adjacent to the proximal teeth, so a blood supply can be reestablished from the alveolar bone to the papillae. No attempt is made to attain primary closure of the socket. Clinically, when an ePTFE membrane becomes exposed, bacteria penetrate the site and require a secondary surgery for removal. "Nonexpanded PTFE barriers are removed when one edge becomes exposed to the oral cavity, generally 3 to 6 weeks after insertion." Hoffmann et al. (2008) evaluated the non-porous, non-resorbable membrame in a retrospective private practice study consisting of 276 sockets in 276 subjects after 8 months of healing. He evaluated the dPTFE (Cytoplast Regentex GBR-200) membrane, a membrane made of high density polytetrafluoroethylene which does not require pnmary closure. The sockets were grouped as either single sockets or side-by-side sockets. His results for ridge height show that about SO% of the sockets had O.S mm of bone loss at the buccal site and SO% of the sockets had 1.0 mm at the buccal site. For ridge width, SO% of the sockets had 0.0 mm bone loss and SO% had O.S mm bone loss.

Histologic evaluation indicate that the newly formed tissue in the socket was mainly regular trabecular bone and typical cells indicating normal healing mechanisms were not impaired. He concluded that the use of dPTFE allows for the preservation of ridge width and height, however the treatment outcome is mainly limited by the architecture of the existing bony walls.

Bio-Col Technique Studies

Sclar (2000) developed the 'Bio-Col' technique for preserving alveolar ridge anatomy following tooth removal in esthetic areas. He says the clinical goal of any ridge preservation technique should be to preserve both the hard and soft tissues following tooth removal, especially the interdental papillae, in such a way to optimize esthetics and function. "Maintaining a stable osteoconductive scaffold within the entire area of the socket that is slowly resorbed and eventually replaced by vital bone and isolating this scaffold from the deleterious effects of the oral environment during healing is an essential biologic consideration (Sclar 2000)."

The steps involved in this technique are as follows: 1) The tooth is extracted atraumatically without flap reflection. 2) Perforation of the socket walls in order to promote bleeding and enhance the invasion of osteoprogenitor cells. 3) The socket is grafted with deproteinized bovine bone mineral (Bio-Oss: Osteohealth Co, Shirley, NY), and isolated from the oral environment with absorbable collagen dressing (CollaPlug, Sulzer Calitek, Inc., Carlsbad, CA). 4) It is sealed with cyanoacrylate, an impervious tissue cement (Isodent: Ellman International, Hewlett, NY). This allows for guided bone regeneration without the need for flap elevation and primary closure, thus preserving the surrounding soft-tissue volume (Sclar 2004). 5) An interim provisional restoration of ovate pontic design that replicates the contours of the tooth that was removed, supports the surrounding soft tissues and avoids implant loading when an immediate implant is placed.

The author's desire in developing the technique was to isolate the grafted socket and obtain a membrane effect without the elevation and advancement of large mucoperiosteal flaps that result in soft-tissue disfigurement and loss of volume at the site. When used in conjunction with immediate implant placement, the Bio-Col technique results in high rates of osseointegration (98.3% 58 sites follow-up time of 10-63 months) and excellent esthetics. Retrospective analysis also revealed a successful osseointegration rate of 94% for 248 sites treated with the Bio-Col in conjunction with delayed implant placement with a follow-up ranging from 6 to 73 months.

Sclar's selection of Bio-Oss as a bone graft material is based on Bio-Oss's osteoconductive properties. Bio-Oss consists of the mineral portion of bovine bone and provides the body with a matrix for bone cell migration. It is also integrated during the natural remodeling process of the human bone and slowly resorbed due to small crystallite size which is comparable to human bone (www.Osteohealth.com).

Fowler and Whicker (2004) revealed a modification to the Bio-Col technique in a case report. They report the modification simplifies the procedure without compromising the esthetic result. The modifications consist of 4 changes to Sclar's description. First, the CollaPlug wound dressing is used in a significantly smaller quantity simply to cover the Bio-Oss graft, not layered to the level of the free gingival margin. On average only

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the terminal 115 of the entire plug is utilized. Second, the horizontal mattress suture is eliminated. Suturing is only done if soft tissue trauma occurred (i.e. the interdental papilla is torn). Third, when a fixed provisional is utilized, the cyanoacrylate is not applied to the CollaPlug. Instead, the provisional is first temporarily cemented and the cyanoacrylate is placed at the gingival margin-pontic interface to "seal" this area. Finally, it is recommended the provisional be removed and modified between 3-6 weeks post-surgery .

As demonstrated by the aforementioned studies, despite the use of ridge preservation techniques to minimize the amount of bone resorption after an extraction, some loss of vertical and horizontal dimensions may still occur. On the other hand, if ridge preservation was not performed, a substantial decrease in the horizontal dimension of the ridge, ranging from 17-63% (0.75 to 6.1 mm) over 4-6 months can be anticipated, which may create enough deficiency of bone to preclude implant placement (Lekovic et al. 1997, Lekovic et al. 1998, Iasella et al. 2003, Schropp et al. 2003, Barone et al. 2008).

Table 8

Ridge Preservation Studies Showing Change Alone

 $*\overline{\text{NG}} = \text{not given in article}$

 \ddagger = no baseline measurements reported, unable to determine percentage

Table 9

Ridge Preservation Studies Showing Ridge Dimensions

Histologic Evaluation of Ridge Preservation

The goal of ridge preservation procedures is to prevent the collapse of the ridge by allowing the alveolar socket to fill in with as much bone volume as possible. The ideal bone grafting material will promote vital host bone to rapidly fill the socket and minimize the loss of ridge dimensions. It is very important to determine histologically how much

bone is present relative to the amount of trabecular space since this measure is a reflection of bone quality that may influence implant placement. A bone quality index has been described by Lekholm and Zarb (1985) which includes Type I bone being homogenous compact bone, Type II being a thick layer of compact bone surrounding a core of dense trabecular bone, Type III being a thin layer of cortical bone surrounding dense trabecular bone of favorable strength and Type IV being a thin layer of cortical bone surrounding a low-density trabecular bone. Type I bone is preferred for implant placement since it has the highest density of cortical bone and Type IV is the least preferred due to its very low density.

Extraction Alone Studies

When extraction sockets are left alone and heal without any type of ridge preservation procedure the amount of vital bone present after 4-8 months of healing ranges from 26-54% with 46-67% of trabecular space (Iasella et al. 2003, Froum et al. 2002, Serino et al. 2003, Barone et al. 2008). In the canine model perfonning extraction alone in 9 sockets, Cardaropoli et al. (2005) reported only 15% vital bone and 85% trabecular space over 6 months. Histologic results from autogenous bone grafts have shown vital bone (osteocytes within the lacunae), non-vital bone (residual graft particles), vascular channels, osteoblasts and secondary osteon formation. Cement lines usually surround the non-vital bone, which joins the immature new bone with the non-vital bone chips (Becker et al. 1994, 1996, 1998)(Table 10).
Allograft Studies

Allografts are usually available in one of two forms: mineralized particulate freeze-dried bone allograft (FDBA) and demineralized particulate freeze-dried bone allograft (DFDBA). FDBA provides an osteoconductive scaffold while DFDBA may provide osteoinductive proteins in addition to the osteoconductive scaffold (Mellonig et a1.l981, Mellonig 1991). The osteoinductive properties of DFDBA have been attributed to the presence of bone morphogenetic protein (BMP). Urist et al. (1971) isolated BMP from human cortical bone. He placed them in ectopic sites in athymic mice and found that they initiated bone formation. The demineralization process of allograft preparation releases BMP and allows osseoinduction to occur. The donor age and health status can also affect the osteoinductive potential. Schwartz et al. (1996, 1998, 2000) found that there is a wide variation in the osteoinductive capabilities of commercial DFDBA from different bone banks. There was an age-dependent decrease in the new bone induction score as measured by histomorphometric analysis. Donors over the age of 50 showed significantly less induction ability, but there were no differences attributable to gender. Studies of demineralized freeze-dried bone allograft (DFDBA) used in ridge preservation procedures have reported conflicting results. Several studies have found that non-vital DFDBA particles are still present in biopsy cores. (Smukler et al. 1999, Froum et al. 2002)(Table 11). It has also been reported that DFDBA has osteoinductive properties and should induce bone growth, but in several histologic samples the DFDBA particles were encapsulated in fibrous connective tissue with no evidence of either osteoblastic or osteoclastic activity (Becker et al. 1994, 1996, 1998). If DFDBA particles do not provide any osteoinductive properties, it is believed they might interfere with normal bone

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formation and may weaken the bone at the grafted site (Becker et al. 1994). The amount of non-vital graft particles remaining relative to the amount of vital bone may be an important factor. Several studies have reported that DFDBA particles do resorb and in some cases fully resorb leaving only vital bone (Vance et al. 2004). Histologic examination reveals that ridge preservation utilizing DFDBA has residual graft particles surrounded by intimately apposed woven and lamellar bone with distinct cement lines and a lack of fibrous encapsulation. Osteoblasts lined endosteal spaces and the new bone marrow exhibited a mild degree of fibrosis without signs of an inflammatory reaction (Brugnami et al. 1996, 1999, Smukler et al. 1999). Vance et al. (2004) examined 12 sockets grafted with a combination of DFDBA and an alloplastic putty consisting of calcium sulfate and carboxymethylcellulose (CaIMatrix®) over 4 months. They reported 61% vital bone, 3% non-vital bone, and 36% trabecular space. The percentage of vital bone present after utilizing DFDBA in ridge preservation ranged from 35 to 60% with only 3-14% having non-vital bone (Smukler et al. 1999, Froum et al. 2002). Becker et al. (1996, 1998) reported more residual graft particles and fibrous encapsulation, which may be due to their failure to use an occlusive barrier membrane.

Freeze-dried bone allograft (FDBA), has also been used in ridge preservation procedures and showed a histologic result of 28% vital bone, 37% non-vital bone and 35% trabecular space over 4-6 months (Iasella et al. 2003). The residual FDBA particles were often surrounded by vital woven or lamellar bone, or were encapsulated in fibrous connective tissue. The residual graft material was higher than the amount with DFDBA, which may be due to the shorter healing period of 4-6 months vs. up to 48 months for DFDBA. Wang et al. (2008), grafted five patients with solvent preserved mineralized

particulate cancellous allograft (Puros). After 5 to 6 months they reported 69% vital bone 3.8% residual graft particles and 27% trabecular space. Comparison of the two grafting materials is difficult since the healing periods are different for each of the studies.

Xenograft Studies

Xenografts, mostly anorganic bovine bone, have also been utilized in ridge preservation procedures with similar results to allografts. Generally, bone encircled and adhered to the grafted particles in a concentric and/or lamellar arrangement. Newly formed bone was observed, mostly in direct connection with the grafted particles (Artzi et al. 1998,2001, Froum et al. 2004)(Table 11). Vance et al. (2004) showed that BioOss® had 26% vital bone with 16% non-vital bone and 58% trabecular space after 4 months of healing. This agrees with a 6-month study of 6 sockets grafted with BioOss® by Zitzmann et al. (1997, 2001) where they reported 27% vital bone, 30% non-vital bone, and 43% trabecular space. **In** contrast, Artzi et al. (2000) in a 9-month study, grafted 15 sockets in 15 patients using BioOss® and reported a much greater percentage of vital bone at 46%, along with 31% non-vital bone, and 23% trabecular space. Froum et al. (2004) in a 6 to 8 month study grafted 8 sockets with a nonresorbable anorganic bovine bone substitute (OsteoGraf $R/N-300$), 4 of which were combined with an ePTFE barrier, and the other 4 with Alloderm (ADM) as a barrier. **In** the OsteoGraf/ePTFE group, there was 18% vital bone, 21% non-vital bone, and 61% trabecular space. In the OsteoGraf/ADM® group, 42% vital bone, 13% non-vital bone, and 45% trabecular space. The difference in the amount of vital bone between the two groups could possibly

be attributed to the choice of barrier used. The vascular channels in the Alloderm may have provided better revascularization compared to the ePTFE barrier. Araujo et al. (2008), grafted one quadrant of fresh extractions sockets in mongrel dogs with Bio-Oss Collagen. After 3 months healing there was 27% bone marrow, 58% vital bone, and 12% residual particles of Bio-Oss Collagen. In a 40 patient study, Barone et al. (2008) compared grafting 20 sockets with OsteoBiol MP3 and a collagen membrane (OsteoBiol Evolution) to extraction alone over 7 months. In the OsteoBiol MP3/Evolution group, they reported 36% vital bone, 29% non-vital bone, and 37% connective tissue. The vital bone of 36% falls in the middle of xenograft histologic studies. The extraction alone group resulted in vital bone of 26% and 59% connective tissue. Neiva et al. (2008) reported on a 24 patient study examining a putty-form anorganic bovine-derived hydroxyapatite matrix combined with a synthetic cell-binding peptide P-15 (Putty PIS) and a bioabsorbable collagen membrane to a bioabsorbable collagen dressing alone. He reported the Putty PIS having 29.92% vital bone, 65.25% bone marrow and 6.2S% nonvital. The bioabsorbable group was reported to have 36.54% vital bone and 62.67% bone marrow.

Alloplast Studies

Alloplastic materials such as bioactive glass, hydroxyapatite (RA) and calcium sulfate have been shown to have vital bone from 2S to 60% (MacNeill et al. 1999, Froum et al. 2002, 2004 Guarnieri et al. 2004, and Mangano et al. 2008). Alloplasts are well tolerated by the host and tend to be osteoconductive in nature rather than osteoinductive.

Guarnieri et al. (2004) in a 10 socket study utilizing medical grade calcium sulfate hemihydrate, found at 3 months that 100% of the graft had been resorbed and that there was 58% vital bone present throughout the preservation site. The site was also devoid of any inflammatory cells and connective tissue. The resorption time with calcium sulfate is much faster than the xenografts or the allografts previously mentioned. Mangano et al. (2008) on the other hand, discussed the slow rate of resorption of hydroxyapatite in a 20 year case report. Mangano et al (2008) reported using very dense HA with a mean size of 1 to 2 micrometers in a mandibular cuspid socket. After 20 years of follow up, the socket demonstrated 25% vital bone, 41% marrow space, and 38% residual HA particles. The author reports the slow rate of resorption due to an intimate binding between a patient's bone and HA particles. MacNeill et al. (1999) compared the osseous healing of 4 different alloplasts: hydroxyapatite (HA, OsteoGraf/P), bioactive glass #1 (BioGran® 300-360 μ m), bioactive glass #2 (PerioGlas[®] 90-710 μ m), and calcium sulfate (Capset[®]) with autogenous bone, in osteotomy sites surgically created in the rabbit tibia over 28 days. All graft sites showed evidence of new bone formation at one month with the Capset plus autogenous bone showing the greatest mean percentage of vital bone (58.8%) and PerioGlas® showing the least (40.4%), while the BioGran and OsteoGraf/P group both showed 41.8% vital bone. Froum et al. (2002) treated 19 human sockets with BioGran® and reported similar results with 59% vital bone, 6% non-vital bone, and 35% trabecular space over 6-8 months. Froum et al. (2004) treated 8 sockets with absorbable HA (OsteoGraf R/LD), 4 of which were combined with an ePTFE barrier, and the remaining 4 with an Alloderm® (ADM) barrier. After 6-8 months of healing, the HA/ADM group showed 35% vital bone, 4% non-vital bone, and 62% trabecular space,

while the HA/ePTFE group showed 28% vital bone, 12% non-vital bone, and 61% trabecular space (Table 11). In contrast, Luczyszyn et al. (2005) grafted 15 sockets in 11 patients using bioabsorbable HA (Algipore®) with an ADM barrier over 6 months. They reported only 1% vital bone, 42% non-vital bone, and 57% trabecular space. Serino et al. (2003), in a non-graft study, treated 34 sockets in 32 patients over 6 months with a bioabsorbable polylactide/polyglycolic acid sponge (Fisiograft®) to encourage vascular ingrowth. They reported 67% vital bone and 33% trabecular space. These results compare well to the results seen by Vance et al. (2004) with DFDBA and the calcium sulfate putty (CaIMatrix®) and Guarnieri et al. (2004) with the medical grade calcium sulfate. In a single case report, Brkovic et al. (2008) evaluated beta-TCP with type I collagen (RTR Cone, Septodont, Saint-Maur-des-Fosses, France) and reported 62.6% vital bone, 21.1% marrow and 16.3% residual B-TCP graft. This is the highest percentage of vital bone reported of the alloplasts.

Summary of Histologic Fndings

When analyzing histologic findings the studies demonstrate that when ridge preservation procedures are performed with a variety of grafting materials, including allografts (DFDBA, FDBA), xenografts (anorganic bovine bone mineral), or alloplasts (hydroxyapatite, calcium sulfate, and polylactide/polyglycolic acid sponge), the percentage of vital and nonvital bone as well as trabecular space varies considerably. The percentage of vital bone ranged from 1-67%, the percentage of non-vital bone ranged from 0-42%, and the percentage of trabecular space ranged from 33-85%.

Comparison of Histologic Data on Extraction Alone studies

Table 11

Comparison of Histologic Data on Ridge Preservation studies

 $*NR = not reported in article$

Summary of Literature Review

Extraction alone studies have utilized both animal and human models. The healing sequence of an extraction socket begins with the formation of a blood clot around day 1, followed by neovascularization around day 3, and subsequent new bone formation starting at around 5-7 days (Clafin 1936, Cardaropoli et al. 2003, Amler 1960, Boyne 1966, Evian 1982). Complete socket fill was noted at day 30 in dogs (Clafin 1936), while only 2/3 of the socket was filled in humans at day 38 (Amler 1960). Mature, lamellar bone was seen as early as 90 days in dogs (Cardaropoli et al. 2003), and this was not present until day 100 in humans (Amler 1960).

Studies of the histologic healing of the extraction sockets have shown that without any type of ridge preservation procedure the amount of vital bone present after 4-8 months of healing ranges from 33-54% with 34-67% of trabecular space (Iasella et al. 2003, Froum et al. 2002, Serino et al. 2003). In contrast, in the canine model, Cardaropoli et al (2003) reported only 15% vital bone and 85% trabecular space after 6 months of healing. Significantly, Araujo et al. (2005), in an 8-week study using the canine model, reported that the bundle bone began to disappear as early as 2-weeks postextraction, and that the buccal wall undergoes a greater amount of resorption than the lingual wall.

Histologic results from autogenous bone grafts have shown mostly vital bone (osteocytes within the lacunae). Studies using allografts (DFDBA, FDBA) for ridge preservation (Smukler et al. 1999, Froum et al. 2002, Vance et al. 2004, Iasella et al. 2003) have yielded variable results. Percentage of vital bone ranged from $30-61\%$,

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% non-vital bone ranged from 3-35%, while percentage trabecular space ranged from 35- 56%. This broad range of results could be attributed to the range in reentry times from 4- 23 months. Ridge preservation studies using xenografts (BioOss®, OsteoGraf) showed similar results to allografts with a range of $18-46\%$ of vital bone, $13-31\%$ of non-vital bone, and $43-61\%$ of trabecular space. A broader range of results was seen with studies using alloplasts (BioGran®, PerioGlas®, Algipore®, hydroxyapatite, calcium sulfate) with re-entry times from 1 to 8 months. From these studies, a range of 1-60% vital bone, 4-42% non-vital bone, and 35-57% trabecular space was reported. Lastly, (Serino et al. 2003), examined the use of a polylactide/polyglycolic acid sponge (Fisiograft®) for ridge preservation and they reported 67% vital bone, an absence of non-vital bone, and 33% trabecular space.

Alveolar ridge resorption has been reported as a common sequelae following tooth extraction. Loss of alveolar ridge width and height can be problematic if a dental implant is selected for tooth replacement. While the dimensions of the healed alveolar ridge determine the feasibility of placement of a dental implant, the immediate, postextraction ridge dimensions may be predictive of the final outcome. In other words, both wide and narrow sockets will lose horizontal width. Thus, if a narrow socket is present initially, the final result may be too narrow to accommodate implant placement. Table 10 summarizes the root dimensions at the cervix as categorized by tooth types.

As is evident from Table 12, different tooth types possess different buccolingual/palatal and mesio-distal dimensions. In general, incisors are the smallest, while molars are the widest in dimension. As a result, ridge preservation becomes increasingly critical for the smaller tooth types (especially mandibular incisors) since even a small amount of horizontal ridge resorption can be detrimental.

Despite the use of a bone graft to preserve alveolar ridge dimensions, most studies have reported a net loss in horizontal and/or vertical ridge dimensions. Simon et al.

(2000) in a 4-month reentry study using particulate DFDBA as an intrasocket and a buccal overlay graft along with a barrier membrane (Resolut XT®); however, reported a mean net gain of approximately 1.1 mm of ridge width.

The goal of ridge preservation is to minimize the amount of ridge resorption after extraction. As was evident from the extraction alone studies reviewed (Lekovic et al. 1997, Lekovic et al. 1998, Yilmaz et al. 1998, Camargo et al. 2000, lasella et al. 2002, Schropp et al. 2003), the change in ridge width following tooth extraction varies substantially, and this broad range (30-60%) may have a profound influence on the future tooth replacement options available.

The University of Louisville has studied ridge preservation since 2003 starting with Iasella. Since that time horizontal ridge width change has ranged from -0.5 to -2.0 mm with a mean of -1.1 mm. The percent change has ranged from -5 $%$ to -21 $%$ with a mean of -13 %. A possible cause of Vance's (2004) small amount of ridge loss could be due to the small amount of time the flap was open, as opposed to Adam's (2005) study which employed a longer surgical procedure (Table 13). Another factor in varying results is tooth type. According to the University of Louisville studies (Table 14), maxillary teeth compared to mandibular teeth and anterior teeth compared to posterior teeth have a greater percentage ridge width loss. Thus, results of a study could vary based on the distribution of teeth in the sample (Table 14). This study resulted in a mean horizontal ridge change of -1.3 mm (15%) for the Bio-Col technique and -1.1 mm (14%) for the PfFE technique.

Horizontal Ridge Width at the Crest for U of L Studies

Mean ± sd in mm

 $\frac{1}{\epsilon}$ = p < 0.05 between initial and 4-month values

Table 14

U of L Studies by Tooth Type

Mean ± sd in mm

CHAPTER II

METHODS

Study design. Twenty-eight patients were invited to participate in this randomized, controlled, single, blinded clinical trial. By random selection, using a coin toss technique, fourteen positive controls were selected to receive a mineralized cancellous particulate bone xenograft (Bio-Oss, Geistlich Pharma, Switzerland), which was covered by a collagen plug, (CollaPlug, Zimmer Dental, California) and used a fullthickness flap technique. Fourteen test patients received an intrasocket cortical mineralized particulate allograft (500 to 800 μ m) (RegenerOss, Biomet 3i, Palm Beach, FL) which was covered with a nonporous PTFE membrane, and also used a full thickness flap technique. Each patient received a post-surgical regimen of 50 mg of doxycycline hyclate (Warner Chilcott Inc. Morris Planes, New Jersey) 1 tab qd for 2 weeks; 375 mg of naproxen sodium (Geneva Pharmaceuticals, Inc. Broomfield, CO) 1 tab q12h for 1 week; chlorhexidine 0.12% (Colgate Oral Pharmaceutical Canton, Massachusetts), twice daily, and analgesics as needed.

At 4-months post-surgery, a trephine core was taken from the grafted site immediately prior to implant placement and was submitted for histologic preparation using hematoxylin and eosin staining after all specimens were collected.

Figure 1

Vertical measures with a stent Horizontal caliper measures Probing measures Standardized radiograph

o

4 to 6 months

Vertical measures with a stent Horizontal caliper measures Probing measures Standardized radiograph Trephine core

Patient Selection

Inclusion criteria

- 1 Have one non-molar tooth requiring extraction that will be replaced by a dental implant. The site must be bordered by at least one tooth.
- 2 Must be at least 18 years old.
- 3) Must sign an informed consent approved by the University of Louisville Human Studies Committee.

Exclusion Criteria

- 1) Debilitating systemic diseases, or diseases that affect the periodontium.
- 2) Molar teeth.
- 3) Allergy to any material or medication used in the study.
- 4) Require prophylactic antibiotics.
- 5) Previous head and neck radiation therapy.
- 6) Chemotherapy in the previous 12 months.
- 7) Long term NSAID or steroid therapy.

Post-Surgical Exclusion

Any site that is excluded after surgery will be reported. Sites were excluded if there was:

- 1) Loss of graft or barrier material.
- 2) Unanticipated healing complications that will adversely affect treatment results.

Presurgical Management

Each patient received a diagnostic work-up including standardized periapical radiographs (Appendix D), study casts, clinical photographs, and a clinical examination to record attachment level, probing depth, recession, and mobility of teeth adjacent to the extracted sites. Customized triad occlusal stents were fabricated on the study casts to serve as fixed reference guides for the measurements (Appendix F).

Presurgical preparation included detailed oral hygiene instructions. Baseline data was collected just before the surgical phase of the treatment. Baseline data included:

Clinical Measurements

- Plaque index: Silness and Löe 1964 (Appendix A).
- Gingival index: Loe $1967 -$ Gingival index (Appendix B).
- Bleeding on Probing Index: Dichotomous index (Appendix C).
- Gingival margin levels: Measured from CEJ to the gingival margin.
- Keratinized tissue: Measured from the gingival margin to the mucogingival junction
- Clinical attachment level: Measured from CEl to the bottom of the clinical periodontal pocket.
- Clinical tooth mobility: Measured by using the modified Miller's Index.
- Horizontal Ridge width: A digital caliper was used to measure total ridge width to the nearest $10²$ mm at the mid point of the alveolar crest and 5 mm apical to the crest, measured post-extraction and prior to implant placement.
- Vertical Change in alveolar crest: Measured post-extraction from the stent to alveolar crest minus re-entry stent to alveolar crest values.
- Radiographic examination: A customized stent was constructed using Triad® light cured resin (Appendix F) and a Rinn-XCP on the patient model (Appendix D) to ensure standardization of the projection.
- Clinical photographs .

Surgical treatment

Patients were anesthetized with 2% lidocaine containing epinephrine in both 1: 100,000 and 1 :50,000 concentrations. A full-thickness, mucoperiosteal flap utilizing papilla preservation was elevated on the buccal and palatal/lingual with long releasing incisions up to the mucogingival junction to expose the alveolar ridge. Teeth were elevated and atraumatically extracted with periotomes, elevators, and forceps. The extraction socket was then curetted to remove all soft tissue. After flap reflection, the triad stent was used to obtain vertical bone height relative to the stent.

A digital caliper was applied to the ridge to measure the total alveolar ridge width at the mid-socket crest and 5 mm apical to the crest. In the PIPE group, the extraction socket was grafted with an intrasocket mineralized cortical particulate allograft composed of cortical chips 500 to 800 μ m (RegenerOss, Biomet 3i, Palm Beach, FL) then covered with a nonporous PIPE membrane. The PTFE membrane was shaped to extend 3 to 4 mm beyond the socket margins and 1.0 mm from the adjacent root. The Plug group received a mineralized cancellous particulate (0.25 to 1.00 mm) xenograft (Bio-Oss, Geistlich Pharma, Switzerland), covered by a collagen plug (CollaPlug, Zimmer Dental, California). The flaps were replaced and sutured with Cytoplast PIPE sutures (Osteogenics Biomedical Lubbock, Tx). Patients were given naproxen 375 mg (Geneva

Pharmaceuticals, Inc. Broomfield, CO), one tab q12h, doxycycline hyclate 50 mg (Warner Chilcott Inc. Morris Planes, New Jersey), 1 tab qd, chlorhexidine 0.12% (Colgate Oral Pharmaceutical Canton, Massachusetts), twice daily, and analgesics as needed.

Patients were seen for postoperative appointments at 2, 4, 8, and 12 weeks. Photographs were taken at each interval. **In** addition, at 4 weeks, patients in the PTFE group were seen for membrane removal. The membranes were removed atraumatically without flap reflection, when possible.

At 4 months, another standardized radiograph was taken. All baseline measurements were repeated. Patients were anesthetized with 2% lidocaine containing both 1:100,000 and 1:50,000 concentrations of epinephrine, and full-thickness mucoperiosteal flaps were elevated on the buccal and palatal/lingual. Papilla were again preserved and not included in the flap design. The acrylic stent was placed and measurements were obtained of vertical ridge height relative to the stent. The digital caliper was used to measure alveolar ridge width at the mid-buccal crestal sites and 5 mm apical to the crest. A blinded examiner performed all clinical measurements for both the initial and final data collection points.

Histologic analysis. A 2.7 X 6 mm trephine (H & H Company Ontario, California) was used with copious chilled irrigation to remove a trephine core from the experimental or control site. The osseous core was removed from the trephine using a periodontal probe that was placed into a window and elevated. The core was subsequently placed directly into a bottle of 10% buffered formalin for histologic preservation. The cores were decalcified and 12 to 15 step serial sections were taken from each

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longitudinally sectioned core. The sections were stained with hematoxylin and eosin. This resulted in 10 slides per patient with at least 4 sections per slide. Vital and non-vital bone and trabecular space quantitation was performed using an American Optical microscope at 150X with a 10 X 10 ocular grid. For each patient 6 of 10 slides were assessed and for each slide at least 100 squares on the ocular grid were counted. A mean percentage of vital and non-vital bone and trabecular space was calculated for each patient.

An osteotomy site was then prepared with a surgical handpiece, using copious irrigation, and each patient received an endosseous root form dental implant. Haps were replaced, and sutured with 4-0 silk sutures. Patients were again given naproxen 375 mg, doxycycline hyclate 50 mg and analgesics as needed.

Statistical analysis. For the statistical analysis, a t-test was used to evaluate the statistical significance of both the within and between group differences for both clinical and histologic data.

CHAPTER III

RESULTS

A total of 22 females and 6 males with a mean age of 54.9, ranging from 32 to 83, were enrolled. The Plug group consisted of 3 maxillary central incisor, 9 maxillary premolars, and 2 mandibular premolars. The PTFE group consisted of 1 maxillary lateral incison, 9 maxillary premolars, and 4 mandibular premolars. There was 1 smoker in the Plug group and 2 smokers in the PIPE group. Smokers were excluded if they smoked more than 112 pack per day. Data from this study was derived from 14 patients, 7 per group, completed by Dr. Elliot Bermudez and the remaining 14 were completed by Dr. Jason Witonsky.

Clinical Indices. Plaque index, gingival index and bleeding on probing had low initial values and did not change significantly ($p > 0.05$, Table 14). There were no statistically significant differences between groups for any of the 3 clinical indices (p > 0.05).

Horizontal Ridge Width Changes. The Plug group presented with a mean initial width at the crest of 8.6 ± 1.0 mm, which changed to 7.3 ± 1.0 mm at month 4 for a mean loss of 1.3 ± 0.9 mm (p < 0.05, Table 15). The PTFE group had a mean initial width at the crest of 7.9 \pm 1.5 mm, which decreased to 6.8 \pm 1.4 mm for a mean loss of -1.1 \pm 1.1 mm ($p < 0.05$). There were no statistically significant differences between groups ($p > 0.05$).

For the Plug group the mean initial width 5 mm apical to the crest was 9.5 ± 1.1 mm, which decreased to 8.0 ± 1.2 mm at month 4 for a mean loss of -1.5 ± 1.0 mm (p < 0.05). The PTFE group had a mean initial width 5 mm apical to the crest of 8.9 ± 1.8 mm, changed to 7.4 ± 1.4 mm for mean loss of -1.5 ± 1.3 mm (p < 0.05). There were no statistically significant differences between groups ($p > 0.05$).

Vertical mid-Buccal Ridge Height Changes. Mid-buccal ridge height for the Plug group had a mean loss of -0.1 ± 1.6 mm (p > 0.05, Table 16). For the PTFE group, mid-buccal height had a mean gain of 0.4 ± 2.1 mm (p > 0.05). There were no statistically significance differences between groups ($p > 0.05$).

Vertical mid-Lingual Ridge Height Changes. Mid-lingual ridge height for the Plug group had a mean loss of -0.3 ± 1.3 mm (p < 0.05, Table 16). For the PTFE group, mid-lingual height had a mean loss of -1.1 ± 2.0 mm (p < 0.05). There were no statistically significance differences between groups ($p > 0.05$).

Vertical Mesial Ridge Height Changes. Vertical mesial ridge height for the Plug group had a mean loss of -0.5 ± 0.7 mm (p < 0.05, table 16). For the PTFE group, mid-lingual height had a mean loss of -0.8 ± 0.9 mm (p < 0.05). There were no statistically significance differences between groups $(p > 0.05)$.

Vertical Distal Ridge Height Changes. Vertical distal ridge height for the Plug group had a mean loss of -0.6 ± 0.6 mm (p > 0.05, table 16). For the PTFE group, midlingual height had a mean loss of -0.7 ± 1.1 mm (p > 0.05). There were no statistically significance differences between groups $(p > 0.05)$.

CEJ to Osseous Crest Changes. The Plug group presented with a mean initial mesial CEJ to osseous crest distance of 2.8 ± 0.5 mm, which increased to 3.3 ± 1.4 mm at month 4 for a mean loss of -0.5 ± 1.0 mm (p < 0.05, table 17). The PTFE group had a mean initial mesial CEJ to osseous crest distance of 3.0 ± 0.6 mm, which increased to 3.2 \pm 0.6 mm for a mean loss of -0.2 \pm 0.9 mm (p > 0.05). There were no statistically significant differences between groups ($p > 0.05$).

For the Plug group there was a mean initial distal CEl to osseous crest distance of 3.0 ± 0.7 mm, which increased to 3.4 ± 1.0 mm at month 4 for a mean loss of -0.4 ± 0.9 mm ($p > 0.05$). The PTFE group had a mean initial distal CEJ to osseous crest distance of 2.9 \pm 0.9 mm, which increased to 3.6 \pm 1.2 mm for a mean loss of -0.7 \pm 1.5 mm (p < 0.05). There were no statistically significant differences between groups ($p > 0.5$).

Histologic evaluation. A high percentage of vital bone was found in both groups (Table 18). Histologic analysis revealed that Plug sites healed with $28 \pm 20\%$ vital bone, 37 \pm 16% non-vital bone, 35 \pm 13% trabecular space. The PTFE sites healed with 35 \pm 21% vital bone, $31 \pm 22\%$ non-vital bone, $34 \pm 10\%$ trabecular space. There were no statistically significant differences between the two groups ($p > 0.05$).

Clinical Indices for Plug and PTFE Sites

Mean \pm sd in index units

 $\mathcal{L}_{\rm{max}}$

Horizontal Ridge Width for Plug and PTFE Sites

Mean ± sd in mm

 $* = p < 0.05$ between initial and 4-month values

Vertical Ridge Height Change for Plug and PTFE Sites

Mean ± sd in mm

 $* = p < 0.05$ between initial and 4-month values

CEJ to Osseous Crest Change at Adjacent Teeth

Mean \pm sd in mm

 $* = p < 0.05$ between initial and 4-month values

Histologic Data for PTFE and Collagen Plug Sites

Mean ± sd

CHAPTER IV

DISCUSSION

In this 4-month randomized, controlled, blinded clinical study of intrasocket ridge preservation in humans, the BioCol technique which utilizes a cancellous particulate xenograft (BioOss) plus a collagen plug (Plug group) was compared to a technique utilizing a mineralized particulate cortical allograft plus a nonporous polytetrafluoroethylene (PTPE) membrane (PTPE group).

In this study there were no statistically significant differences in the change in mean horizontal ridge width between groups. At the crest and 5 mm apical to the crest both groups showed significant loss ($p < 0.05$), each losing -1.5 mm of mean ridge width.

Ridge preservation studies show less loss of mean ridge width when compared to treatment by extraction alone (Lekovic et al. 1997, Lekovic et al. 1998, lasella et al 2003). Extraction alone most often leads to extensive ridge resorption. In general, the longer the time period studied, the greater the ridge resorption reported (Lekovic et al. 1997, Lekovic et al. 1998, Schropp et al. 2003, lasella et al. 2003). The ridge width dimension is compromised to a greater degree than ridge height, which is generally minimally affected. Ridge preservation does not totally eliminate loss of ridge width and most studies show that some loss still occurs. Previous studies have shown that extraction alone leads to a mean loss of 43% ridge width versus 12% loss for ridge preservation (Tables 6, 7, 8, 9).

This study showed more loss of ridge dimension with a preservation procedure than 1 of the earlier studies at this institution, Vance et al. (2004), but less than 3 previous studies; Adams, lasella et al. (2003), and Siu, (Table 16).

Both groups lost mean ridge height at all locations (mid-buccal, mid-lingual, mesial and distal) except the mid-buccal site for the PTFE group, which gained 0.4 mm. The PTFE group showed a statistically significant loss of -1.1 mm at the mid-lingual site and -0.8 on the mesial ($p < 0.05$). The plug group showed a statistically significant loss of -0.5 mm on the mesial and -0.6 mm on the distal ($p < 0.05$). None of these changes were statistically significant between groups $(p > 0.05)$.

This study evaluated loss of crestal width in extraction sites with at least one adjacent tooth. Twelve of 14 sites had 2 adjacent teeth. Loss of crestal width may be greater when there are no adjacent teeth, especially when all teeth in an arch are being removed. Thus, the means and ranges reported in this study may not be generalizable and should be limited in application to sites with adjacent teeth. Further study is warranted to document the resorptive response when an arch is edentulated.

The mean CEl to osseous crest distance changed 1 mm or less for both the Plug and PTFE groups with no statistically significant differences between groups ($p < 0.05$).

The PTFE group had more vital bone (35 vs 28%) and less non-vital bone (31 vs. 37%) than the Plug group. The xenograft used for the Plug group typically resorbs slowly and this results was not unexpected. Use of the allograft resulted in the presence of more vital bone in the area of implant placement. The significance of increased vital bone for long term implant success or survival has not been established, however, most clinicians prefer to have increased vital bone.

Based on the results of this study, the change in ridge dimensions did not show any statistically significant differences between the Plug or PTFE ridge preservation techniques. Both treatments were effective in the preservation of horizontal and vertical ridge dimensions.

CHAPTER V

CONCLUSIONS

Within the limits of this study design and sample size it may be concluded that:

- 1) Mean crestal ridge width was preserved for both the Plug and PTFE groups and there were no statistically significant differences between groups ($p > 0.05$).
- 2) There was a trend toward greater loss of mean mid-buccal ridge height for the Plug group, although there were no statistically significant differences between groups $(p > 0.05)$.
- 3) The mean CEJ to osseous crest distance showed only a minimal loss of 1 mm or less for both the Plug and PTFE groups and there were no statistically significant differences between groups ($p > 0.05$).
- 4) The PTFE group had more vital bone and less non-vital bone than the Plug group, however, there were no statistically significant differences between groups ($p >$ 0.05)

Figure 2. a) Pre-op PTFE; b) Cortical allograft;

Figure 2. c) PTFE membrane; d) Pre-op 4-month re-entry.

Figure 3. c) Collagen plug; d) Pre-op 4-month re-entry..

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Appendix A

The Plague Index

The plaque index of Silness and Loe (1964) was measured. Scores were as follows:

- 0- No plaque
- 1 A film of plaque adhering to the free gingival margin and adjacent area of the tooth. The plaque may be seen in situ only after application of disclosing solution or by using the probe on the tooth surface.
- 2 ~ Moderate accumulation of soft deposits within the gingival pocket, or on the tooth and gingival margin, which can be seen with the naked eye.
- 3 Abundance of soft matter within the gingival pocket and/or on the tooth and gingival margin.

Each gingival unit (buccal, lingual, mesiobuccal, distobuccal, mesiolingual, and distolingual) of the individual tooth was given a score from 0-3, called the plaque index for the area. The scores from the 6 areas of the tooth were added and divided by 6 to give the plaque index for the tooth.

AppendixB

Gingival Index

The gingival index of Loe (1967) was measured for the extracted tooth and any adjacent teeth. Scores were be recorded as follows:

- $0 =$ Normal gingiva.
- $1 =$ Mild inflammation $-$ slight change in color slight edema, no bleeding on probing.
- $2 =$ Moderate inflammation redness, edema, and glazing, bleeding on probing.
- 3 = Severe inflammation marked redness and edema, ulceration and tendency to spontaneous bleeding.

Each gingival unit (mesiobuccal, buccal, distobuccal, distolingual, lingual, mesiolingual) of the tooth was given a score O~3. The scores for each unit were added together and divided by 6 to give the gingival index for that tooth. The score of the test tooth and the two adjacent teeth were added and divided by 3 to give the gingival index for the test of control sites.

Appendix C

Bleeding on Probing Index

Dichotomous scoring was used for bleeding on probing:

 $0 = No$ bleeding;

1 = Bleeding on probing to the bottom of the pocket.

AppendixD

Standardized Radiographic technique

An occlusal stent was used to provide a stable foundation for the radiograph holder. A light cured resin material was placed on a Rinn radiograph holder and positioned to allow as near as possible paralleling technique. This material was light cured so that standardized radiographs can be compared. Radiographs were taken at baseline and 4 months.

AppendixE

Arithmetic determinations:

- **Ridge width (Post-extraction) =** A digital caliper was used to measure total ridge width to the nearest 10^{-2} mm at one point, mid socket, at the alveolar crest and 5 mm from the alveolar crest
- **Ridge width (4 month re-entry) =** Again, a digital caliper measured total ridge width to the nearest $10⁻²$ mm at one point, mid socket, at the alveolar crest and 5 mm from the alveolar crest.
- **Change in alveolar crest height = Initial: stent to alveolar crest minus re-entry stent to** alveolar crest.

Appendix F

Stent fabrication

Rigid stents were made of 3 mm thick light cured resin material in order to provide reproducible measurements. The tooth to be extracted was ground off the model and the light cured resin material was pressed over a cast. Three channels were prepared on the labial and three on the palata/lingual aspect of the stent in which a North Carolina periodontal probe was placed so that mesial, mid and distal measurements could be made on the labial and palata/lingual aspects of the crestal bone. Additionally, two channels were also prepared on the occlusal portion of the stent to provide measures of mesial and distal occlusal ridge height. Holes were prepared with a high-speed hand-piece. **In** this way, reproducible probing spots and directions of probe insertions were possible.

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