RIDGE AUGMENTATION USING DFDBA AND CORTICAL CANCELLOUS CHIPS IN A THERMOPLASTIC MATRIX (REGENAFORM™)

By

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A THESIS PRESENTED TO THE GRADUATE SCHOOL
OF THE UNIVERSITY OF FLORIDA IN PARTIAL FULFILLMENT
OF THE REQUIREMENTS FOR THE DEGREE OF
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This document is dedicated to my family, instructors, and fellow residents.

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ONLAY RIDGE AUGMENTATION UTILIZING DFDBA AND CORTICAL CANCELLOUS CHIPS IN A THERMOPLASTIC MATRIX (REGENAFORM™)

By

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Major Department: Periodontics

Background: The objectives of this study were to determine if the use of a proprietary preparation of DFDBA and cortical cancellous chips in a thermoplastic matrix (Regenaform™) for onlay ridge augmentation procedures yields adequate volume of bone formation for implant placement. As endosseous dental implant placement is often compromised in atrophic alveolar ridges, augmentation is often required. Autogenous onlay blocks require a second surgical site and can have significant postoperative sequelae. A tissue banked alternative with comparable efficacy to that of autogenous bone grafting would offer an attractive clinical alternative.

Materials and methods: Eleven patients (4 males and 7 females) with a total of 16 sites requiring a ridge augmentation procedure prior to implant placement were selected. The mean age was 59 years of age. Regenaform™ block grafts were used alone with placement of a resorbable collagen membrane. Augmentation procedures were performed using full thickness flap reflection, cortical penetrations, graft adaptation, collagen

membrane adaptation, and tension free primary closure. Using a custom fabricated stent, measurements were taken pre-graft, post-graft, and at 6 months to record bone gain or loss and to evaluate the effectiveness of this material in ridge augmentation surgery.

Results: The range of horizontal bone augmentation obtained using this graft material was 1-6 mm. Mean bone augmentation horizontally was 3.66 mm (2.64mm in the maxilla and 4.28mm in the mandible). The range of vertical bone augmentation obtained was 0-3 mm with a mean of 0.54 mm. A difference in resorption, though not statistically significant, was seen between the maxilla and mandible at the horizontal measurements (38% graft resorption for maxilla and 29% for mandible). A total of 25 implants were placed into the grafted sites and to date there have been 0 failures.

Conclusion: In the present study, the principle of GBR was applied using Regenaform™ in conjunction with a resorbable collagen membrane for the purpose of placing dental implants. While previous studies report greater resorption of bone grafts in the maxilla as opposed to the mandible , there was no statistical difference between these two anatomic areas in our study in this regard (max: 38%; man: 29%). In all cases with uneventful healing, sufficient bone regeneration was obtained with this procedure to allow for implant placement. It was demonstrated that Regenaform™ used as an onlay graft material could minimize or eliminate the need for a donor site. This study shows that Regenaform™ in combination with a collagen membrane provides a predictable method for regenerating vertical bone up to 3 mm, with a mean of 0.54 mm and up to 6 mm of bone horizontally with a mean of 3.66 mm (maxilla= 2.64 mm and mandible= 4.28 mm).

CHAPTER 1
INTRODUCTION

Endosseous dental implant placement is often compromised when placed in atrophic alveolar ridges. Ridge augmentation procedures are designed to widen ridges prior to implant placement. Traditionally, onlay ridge augmentation procedures have consisted of using an autogenous block graft from a separate surgical area such as the ramus, chin, posterior ridge, and on occasion, the tibia, iliac crest, or ribs. This donor site can be uncomfortable to the patient and leaves a potential for post-surgical complications. The need for a donor site would be reduced if a graft material such as Regenaform™ were shown to provide adequate volume and quality of new bone in previously atrophic sites.

CHAPTER 2
BACKGROUND

The success and long term prognosis of endosseous implants in the treatment of fully or partially edentulous patients has been well documented.[1,2,3] Adequate volume and quality of bone in the edentulous area is required for acceptable functional and aesthetic results.[4] A minimum of 5 mm of ridge width is required for implant placement.[5] (using narrow diameter implants) When placing standard diameter implants, 4 mm, it has been stated that a minimum of 6 mm of ridge width is required.[6,7] Insufficient bone dimensions result from excessive alveolar bone resorption that can occur following extractions, trauma, or pathosis. This may prevent placement of fixtures in acceptable locations, angulations, and lengths. As a result, endosseous dental implant placement is often compromised when placed in atrophic alveolar ridges.

Ridge augmentation procedures are designed to widen ridges prior to implant placement. Various grafting procedures have been utilized for grafting an edentulous ridge, including, allograft, autograft or xenograft with or without a titanium re-enforced membrane, ridge-splits, distraction osteogenesis, and onlay grafting with an autogenous or allograft bone block. Traditionally, onlay ridge augmentation procedures have consisted of using an autogenous block graft from a separate intra-oral surgical area such as the ramus, chin, posterior ridge, or from extra-oral sites such as the tibia, iliac crest, or ribs.[8,9,10,11,12] The need for a second surgical site could be eliminated if a graft material such as Regenaform™, were shown to provide adequate volume and quality of new bone in previously atrophic sites.

Graft Material

Regenaform™ was developed at the University of Florida Tissue Bank, now known as Regeneration Technologies Inc. It is a bone paste allograft comprised of decalcified freeze dried bone allograft (DFDBA) and 1-3mm size cortical cancellous chips in a water insoluble thermoplastic porcine collagen gelatin carrier that resorbs in approximately 10 days. It has a rigid rubbery consistency at room and body temperature and becomes soft and moldable when warmed to 43 - 49º C in a heated water bath for approximately 15 minutes. The DFDBA in Regenaform™ processed bone has proven to be osteoinductive using the Urist- Strates model.[13] Each batch is tested for osteoinductivity by implanting the DFDBA intramuscularly in rats and checking for new bone formation.

History of Ridge Augmentation

The same basic principle of guided tissue regeneration (GTR) has been used to regenerate new bone in alveolar defects.[14] Nyman et al (1990) was the first to publish the enlargement of a reduced alveolar ridge.[15] Siebert J, Nyman S (1990) were the first to publish a study that evaluated the potential to reconstruct localized ridge defects with bone (dog model).[16] Buser, Bragger, Lang, Nyman (1990) published 9 successful cases of ridge augmentations followed by implant placement in 7 humans.[17] Since then, Becker & Becker, Jovanovic, Buser et al have all documented successful regeneration of such of reduced ridges implementing the principles of GTR. Ridge augmentation concepts employed the same principles of specific tissue exclusion seen in GTR, but were not associated with teeth. Therefore, the term applied to this procedure was guided bone regeneration (GBR).

Membranes

Resorbable and non-resorbable membranes have been shown to be effective in GBR procedures.[18] Ridge augmentation can be predictably accomplished provided that the membrane is properly adapted and complete closure is obtained throughout the healing phase.[19] If the membrane becomes exposed there is an increased possibility of resorption and lack of continuity between the graft and host bone.[20]

Healing in Bone Regeneration

There are three mechanisms of healing that can take place with a bone graft. Osteogenesis is when new bone is formed from live cells (autograft). Osteoconduction occurs as a result of an inert scaffold which permits the in-growth of surrounding host bone. And, osteoinduction, which is the formation of new bone by active recruitment of host cells with the potential for osseous repair. For optimal bone regeneration to take place, Lang et al established that an undisturbed healing period of at least six months is required.

There are six generally agreed upon requirements for bone regeneration to take place and are shown in below (Table 2-1). [21]

Table 2-1: Requirements for Bone Regeneration and Surgical Procedures That Meet the Required Criteria.

Biological Requirements	Surgical Procedure
Blood Supply	Cortical perforations
Stabilization	Fixation screws, membranes
Osteoblasts	Autogenous bone graft, cortical perforations
Confined space (soft tissue exclusion)	Barrier membrane
Space maintenance	Tenting screws, Ti re-enforced membranes, bone graft materials
Wound coverage	Flap management, tension-free suturing

CHAPTER 3
AIM OF STUDY

The aim of the study was to determine volume changes of bone following ridge augmentation with Regenaform™ by conducting a clinical trial compromised of a series of augmentation surgeries to include collection of clinical measurements of the ridges prior to and after a six month healing. Specific objectives are listed below:

1. To clinically measure the amount of horizontal and vertical bone gain obtained using this bone allograft at different points along the ridge.

2. To determine the:

- Amount of bone grafted.
- Amount of bone gain.
- Amount of graft resorption.

3. To assess the quality of bone at implant placement following a six month healing period.

4. To compare the results obtained in the maxilla versus the mandible.

CHAPTER 4
NULL HYPOTHESIS

This material is effective in ridge augmentation for the purpose of future implant placement. There is a correlation between graft resorption and location of graft placement. The maxilla exhibits greater percentage of graft resorption.

CHAPTER 5
MATERIALS AND METHODS

Among the patients referred to the University of Florida, Graduate Periodontics clinic for implant placement, 14 patients that required ridge augmentation procedures prior to implant therapy were included in this study. Four of these patients required multiple areas of ridge augmentation resulting in 19 surgical sites. If a patient required more than one site, they were separated by at least a single tooth and were performed at different times to allow healing of the surrounding tissues.

Inclusion Criteria

The following inclusion criteria were used:

- Partial edentulism with ridge deficiency.
- Both maxillary and mandibular arches were included.
- Horizontal and/or vertical deficiencies were included.
- Future implant treatment planned for site.
- Age limited to a minimum of 18 years of age.
- Males and females included.

Exclusion Criteria

The following exclusion criteria were used:

- Over a pack a day smokers.
- Diabetics (uncontrolled) or other severe systemic diseases.
- Pregnant or lactating.
- The need for antibiotic prophylaxis.
- Any other conditions contraindicating periodontal surgery.
- Unable to make all scheduled post-ops.
- Diagnosed with aggressive periodontitis.
- Patient allergic to porcine products.
- Patients unwilling to have porcine products used on them.

Sample Selection

Of the 19 surgical sites, 8 were on the maxilla and 11 on the mandible. Of the 14 patients selected, 4 were males and 7 females. Only one patient reported smoking. It was in the form of 2-3 cigars per week. Ages range from 26-77 years of age with a mean age of 56.

Two females (equaling 5 sites) reported taking oral bisphosphonates for osteoporosis for over a 2 year period.

The sites were classified using the Siebert classification of ridge defects. [22]

Table 5-1. Siebert Classification

Classification of Site	Description of Loss
I	Buccolingual with normal ridge height
II	Apicocoronal with normal ridge width
III	Buccolingual and apicocoronal

Table 5-2. Distribution of sites according to Siebert classification

Classification of Site	# sites in each class
I	6
II	0
III	13

Custom Stents

Alginate impressions were taken prior to surgery and diagnostic casts were poured in microstone. Triad™ acrylic was used to “build up” the ridge on the casts and allow room for graft material underneath the stent. Measurements were collected using a custom fabricated stent. 1.0 mm thick vacuform plastic sleeves were used to make custom stent. A hole was created in the stents directly over the ridge in the area of greatest deficiency and was designated the Vertical point. The Horizontal points were created through the facial of the stents in a corono-apical direction at: 4 mm & 8 mm apical to the alveolar crest. These holes correlated to the area of greatest horizontal

deficiency. Holes were created using a 169L bur. Measurements were then taken using a UNC15 probe placed through the holes created in the stent. The probe was maintained as close to perpendicular to the stent as possible. Measurements were taken three times at each site: (1)after flap reflection but before graft placement, (2) after graft placement, & (3) at 5-7 month re-entry for implant placement.

Surgical Technique

The surgical procedures were carried out by two of the authors (A.S. & D.D). All surgeries were performed under local anesthesia. Crestal incisions were made to the lingual/palatal of the ridge while still in keratinized gingiva with divergent vertical incisions only performed when needed to release tension on the flaps. Full thickness flaps were reflected (Figure 2). After flap reflection, a UNC15 mm probe was used to record measurements, to the nearest millimeter, through the holes created in the stent, 1 vertical point and 2 horizontal points (Figure 3). The cortical bone was perforated using a #2 round bur on high speed handpiece. Depth of penetration was extended only through the cortical plate (Figure 4). Decortication is performed to allow angioneogenesis into the grafted site.

A 0.5, 1, or 2 cc block was selected depending on number of implants desired and size of augmentation required. Following cortical penetrations, the graft material was then placed in a water bath and heated between 43 - 49º C for 10-15 minutes. The graft was removed from the water bath once it became depressible to the touch. The graft material was then molded and adapted to the defect (Figure 5). Once cooled to room temperature, the graft material became solid allowing it to maintain the shape of the defect and/or desired augmentation. Using the same stent, the measurements were taken after graft placement, 1 vertical and 2 horizontal (4 & 8 mm). Type I bovine collagen

resorbable membranes were used for graft stabilization and soft tissue exclusion (Figure 6). Two different brands of membranes were used; BioMend Extend® and Ace®. One site had an Ace® collagen membrane used. The remaining 18 had BioMend Extend® membranes used. Prior to suturing, periosteal releasing incisions were performed until the flap passively covered the grafted site. Tension free primary closure of the surgical site was obtained (Figure 7). Suturing was completed using interrupted and mattress vicryl sutures. Temporary removable partial dentures were adjusted until there was no contact with the grafted area (Figure 8). Patients were asked to use the RPD as seldom as possible.

Post-Operative Care

Post-operative antibiotics prescribed were: Augmentin 500 mg TID or Clindamycin 300 mg 1q6h for the first week of healing. Patients were instructed not to chew on the area for approximately 2 weeks. Chlorhexidine (0.12%) rinse twice a day was instituted for the first week. Patients were prescribed 600-800 mg of ibuprofen 1q6-8h for the first 3 days to help minimize swelling of the area. Analgesics were prescribed when needed. Patients were seen for suture removal at 10-14 days. Further recall appointments were scheduled at 1 month, 3 month, 5 month, & 6 months. At the 5 month recall, a panoral radiograph was taken and impressions were obtained. These were used to fabricate a surgical guide for implant placement. At 5-7 months the sites were re-entered (Figure 9). The ridge was measured at the same points using the same custom stent as at the time of graft surgery. Afterwards, implants were placed using one of the available implant systems (3i Innovations™, Straumann™, Astra Tech™, or Nobel Biocare™).

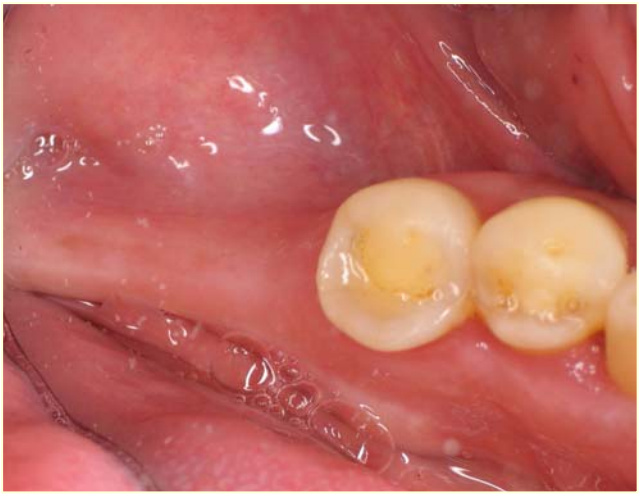


Figure 5-1. Ridge prior to ridge augmentation

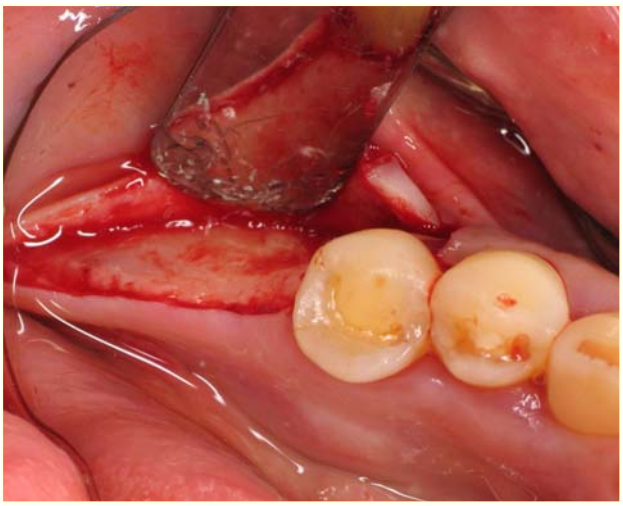


Figure 5-2. Mucoperiosteal reflection

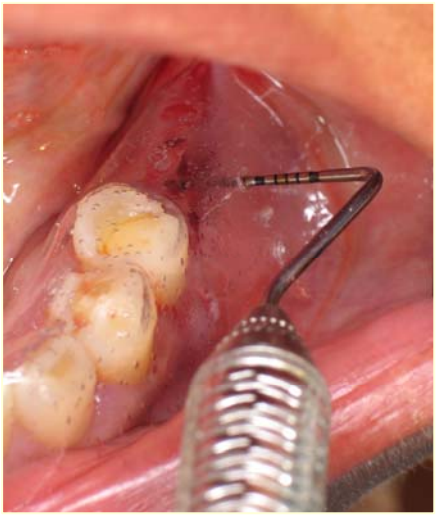


Figure 5-3. Collection of measurements using custom stent

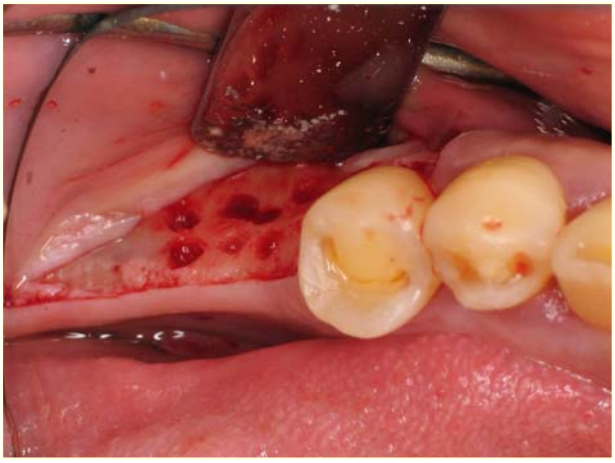


Figure 5-4. Cortical penetrations

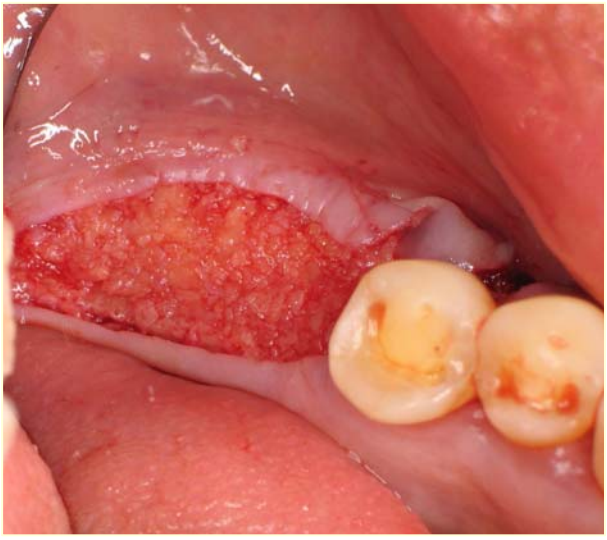


Figure 5-5. Graft adaptation

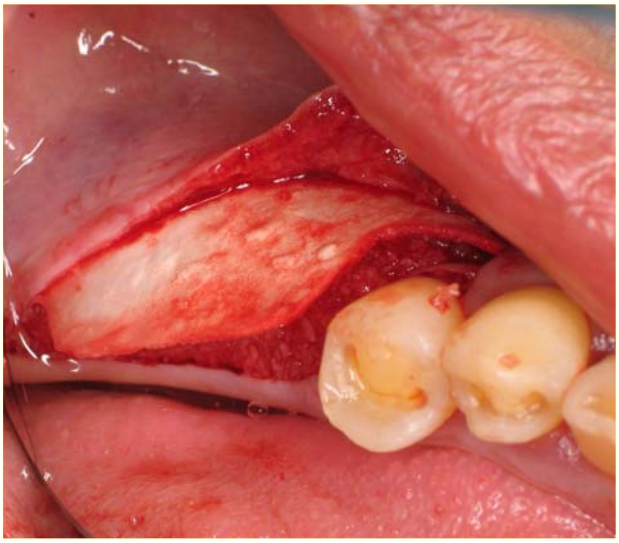


Figure 5-6. Collagen membrane placement

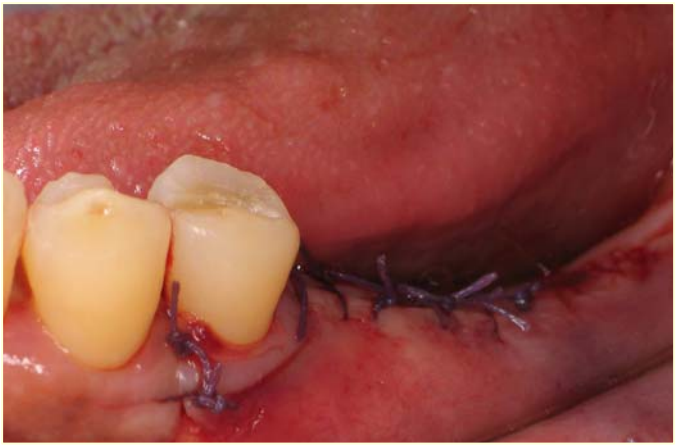


Figure 5-7. Tension-free closure

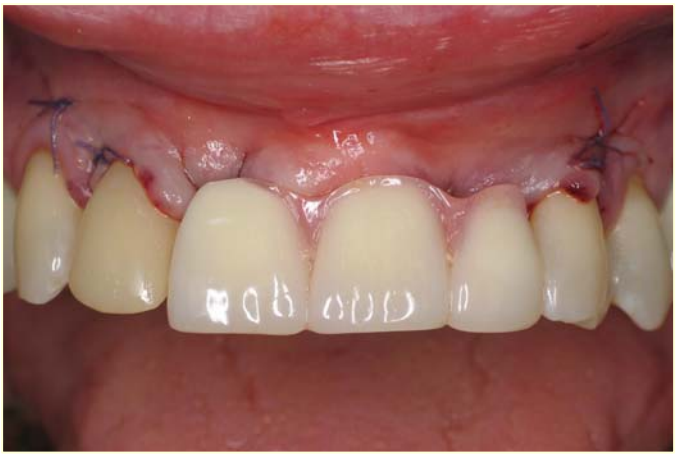


Figure 5-8. This figure shows an example of a temporary removable partial denture. Temporary RPDs were only made for Max anterior cases.

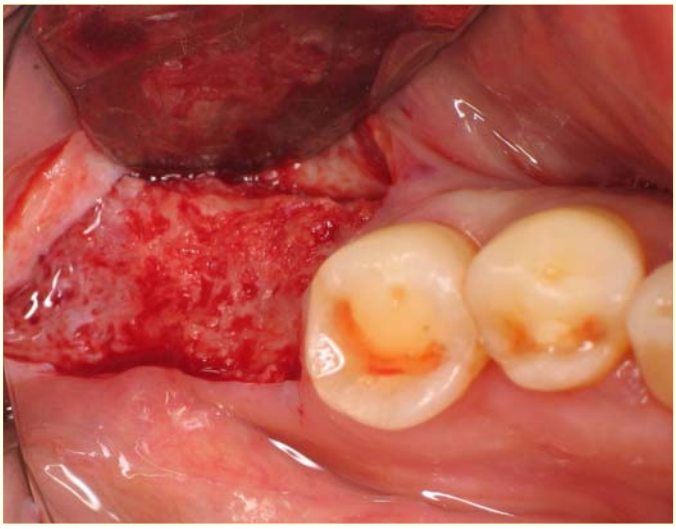


Figure 5-9. Re-entry at 6 months for implant placement

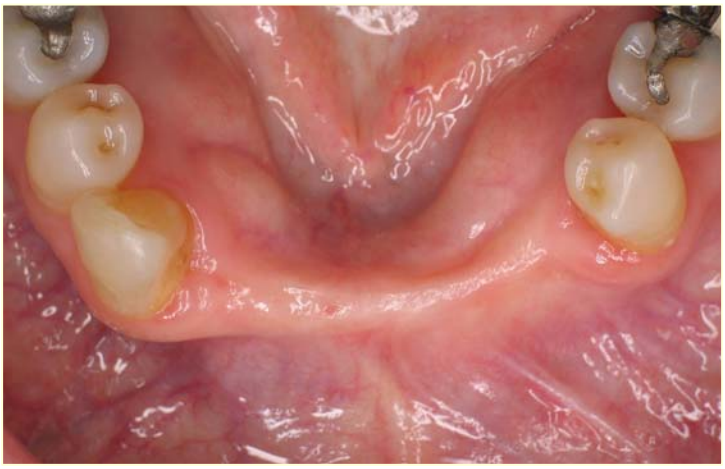
CHAPTER 6
RESULTS

Of the 14 patients that entered the study, 11 (4 males and 7 females) returned for implant placement. One patient was dropped from the study due to inability to re-enter within the 5-7 month period. One patient moved out the area. And, one patient dropped out due to changes in their finances that did not allow implant placement. From the 11 returning patients, there were a total of 16 augmented sites. Ages range from 43-77 years of age with a mean age of 59.

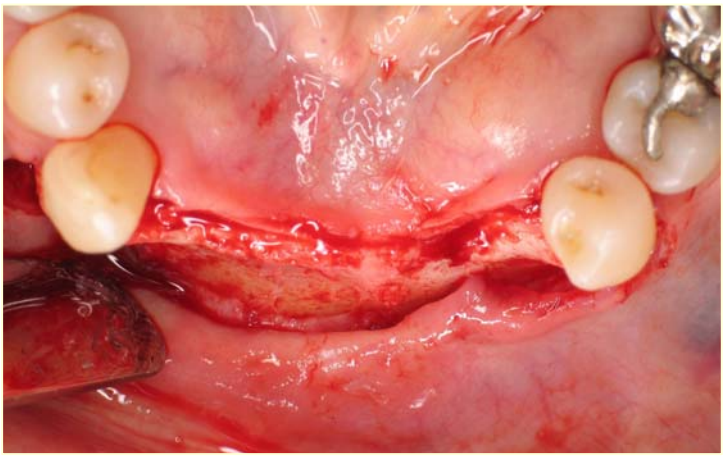
Two patients experienced membrane exposure, one of these patients experienced a post-operative infection evident by pus flow from the vertical releasing incision. The patient was seen at the 1st recall and given another week of antibiotics. This time, clindamycin was prescribed. The infection was not clinically present by the 1 month recall and the graft did not have to be removed. Subsequent implant placement was not possible at re-entry due to excessive resorption and the site was grafted a second time. This site will be referred to as IC (infected case) for the rest of this presentation. The other patient experienced a larger membrane exposure that was managed by instructing patient to saturate the exposed area with chlorhexidine 3 times per day. By the first month recall, the site had closed and the membrane was no longer visible.

The results will be discussed in terms of amount bone gain (regeneration), amount of graft resorption, amount grafted, % of graft resorption, quality of bone, and implant survival.

Figures 6-1. Example of an experimental case. Complete series. (a) Multiple tooth site #22-26. (b) Crestal incision with vertical releasing incisions #21 distal and #27 distal. (c) Cortical perforations. (d) Adaptation of graft material to defect and desired augmentation. (e) Resorbable collagen membrane trimmed to fit over graft site. (f) Tension free primary closure using mattress and interrupted sutures. (g) Graft site after 6 month healing. (h) Six month re-entry for implant placement. (i) Implant placement. (j) Radiograph taken 2 months post implant placement.



(a)



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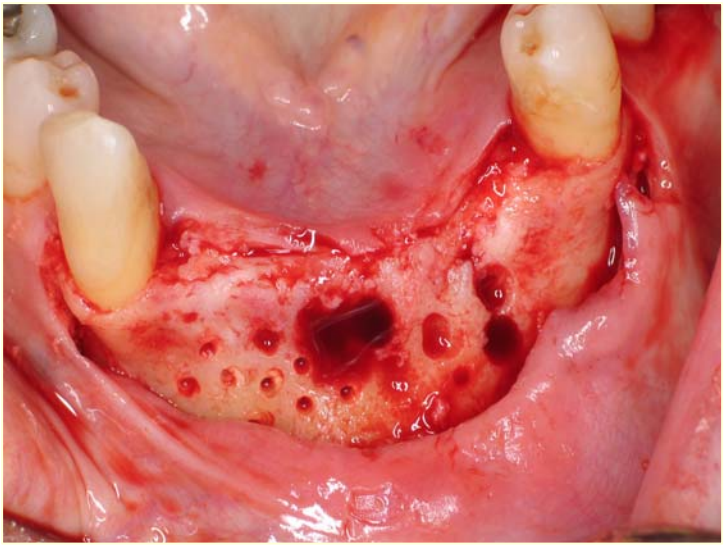

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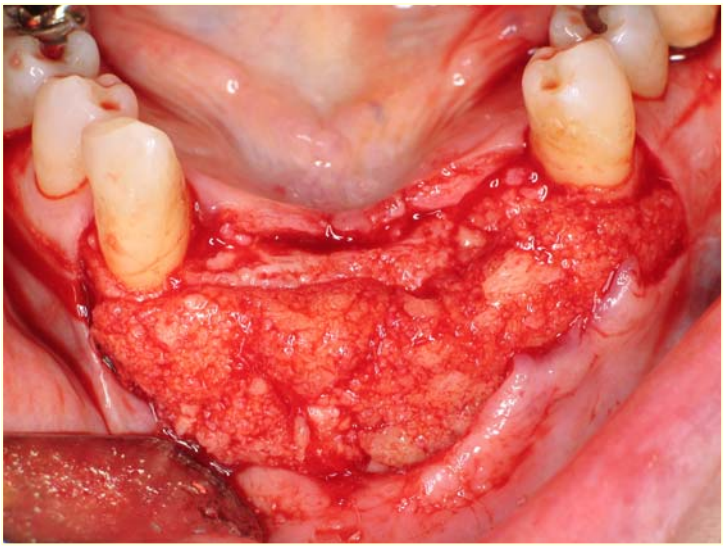

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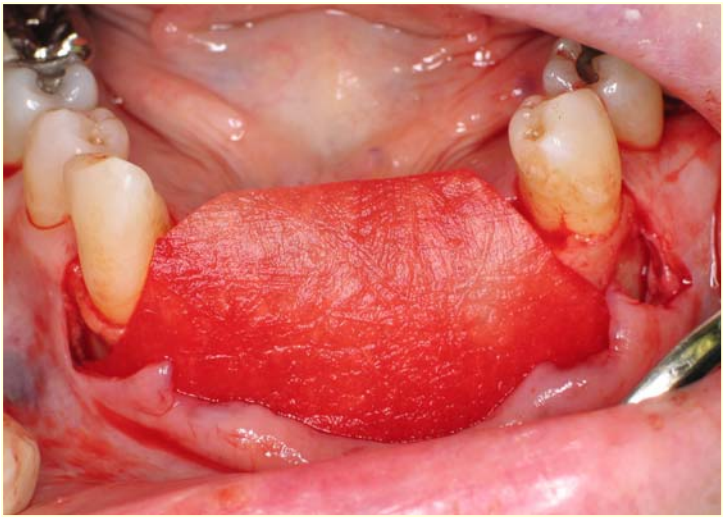

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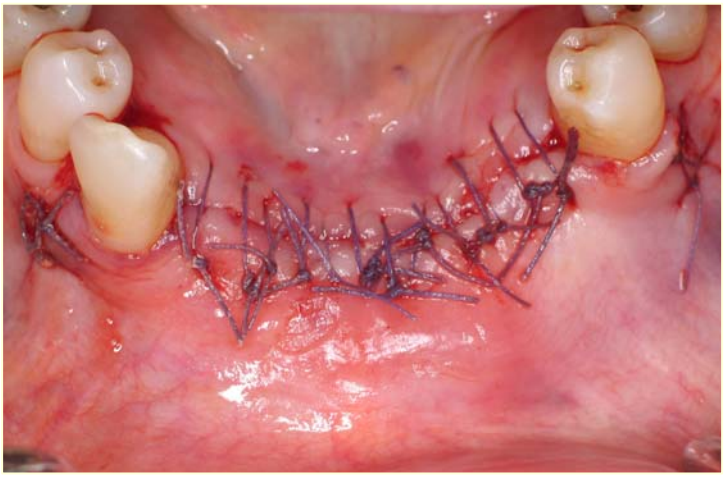

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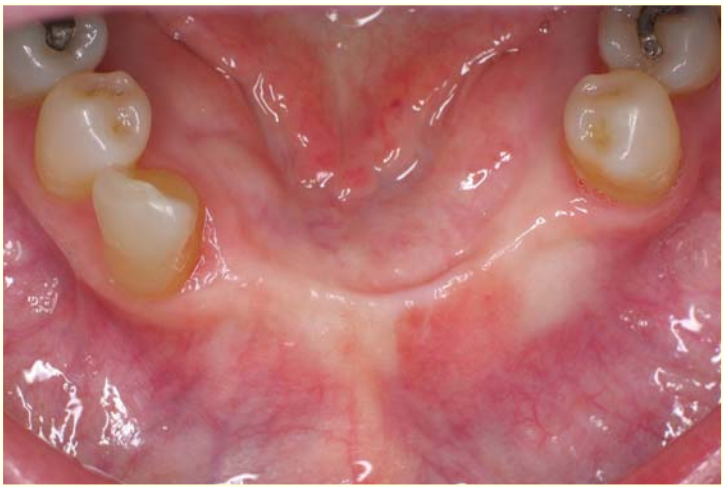
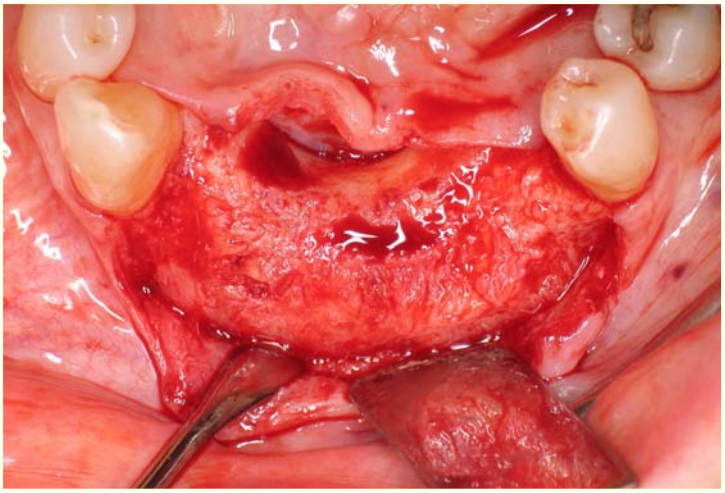


(g)



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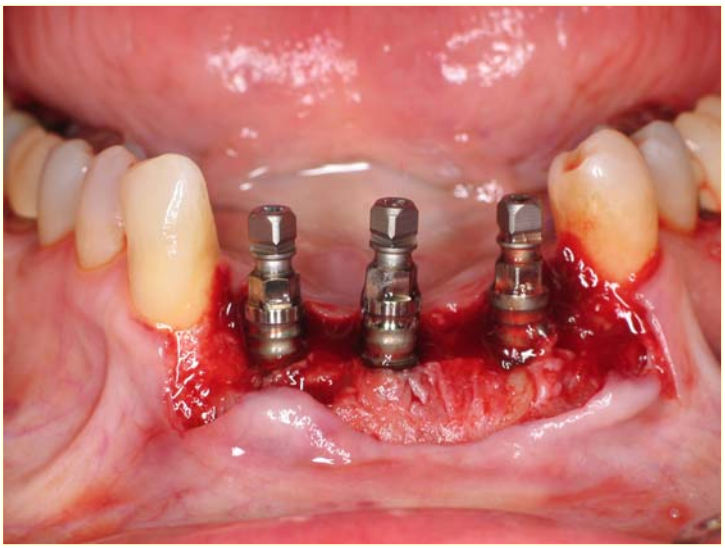
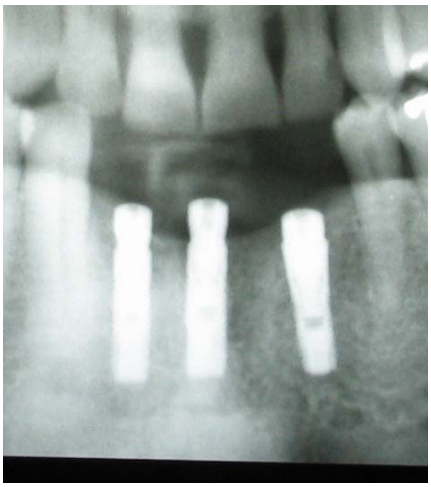


(i)



(j)

Table 6-1.Bone Gain—RANGE

Measurement point	Max or Mand (n)	Range (mm)
Vertical Point	Max(6)	0-1
	Mand(7)	0-3
	Max & Mand(13)	0-3
Horizontal 4mm point	Max(6)	2-3
	Mand(10)	1-6
	Max & Mand(16)	1-6 w/o IC= 3-6
Horizontal 8mm point	Max(5)	2-4
	Mand(10)	3-6
	Max & Mand(15)	2-6
Total horiz. (4&8 mm)	Max(11)	2-4
	Mand(20)	1-6
	Max & Mand(31)	1-6 w/o IC= 1-6

Table 6-2.Bone Gain—AVERAGE

Measurement point	Max or Mand (n)	Average (mm)
Vertical Point	Max(6)	0.33
	Mand(7)	0.83
	Max & Mand(13)	0.54
Horizontal 4mm point	Max(6)	2.2
	Mand(10)	4.0 w/o IC= 4.3
	Max & Mand(16)	3.3 w/o IC= 3.5
Horizontal 8mm point	Max(5)	3.2
	Mand(10)	4.1 w/o IC= 4.2
	Max & Mand(15)	3.8 w/o IC= 3.9
Total horiz. (4&8 mm)	Max(11)	2.6
	Mand(20)	4.1 w/o IC= 4.3
	Max & Mand(31)	3.6 w/o IC= 3.7

Table 6-3. Resorption—RANGE

Measurement point	Max or Mand (n)	Average (mm)
Vertical Point	Max(6)	0-4
	Mand(7)	1-4
	Max & Mand(13)	0-4
Horizontal 4mm point	Max(6)	0-3
	Mand(10)	1-4 w/o IC=1-4
	Max & Mand(16)	0-4
Horizontal 8mm point	Max(5)	0-4
	Mand(10)	0-3 w/o IC= 0-3
	Max & Mand(15)	0-4
Total horiz. (4&8 mm)	Max(11)	0-4
	Mand(20)	0-4 w/o IC=0-4
	Max & Mand(31)	0-4 w/o IC= 0-4

Table 6-4 Resorption—AVERAGE

Measurement point	Max or Mand (n)	Average (mm)
Vertical Point	Max(6)	2.0
	Mand(7)	1.6
	Max & Mand(13)	1.8
Horizontal 4mm point	Max(6)	2.0
	Mand(10)	2.0 w/o IC=1.89
	Max & Mand(16)	2.0 w/o IC=1.93
Horizontal 8mm point	Max(5)	1.2
	Mand(10)	1.40 w/o IC= 1.44
	Max & Mand(15)	1.33 w/o IC= 1.36
Total horiz. (4&8 mm)	Max(11)	1.6
	Mand(20)	1.7 w/o IC= 1.7
	Max & Mand(31)	1.7 w/o IC= 1.7

Table 6-5 Amount Grafted—RANGE

Measurement point	Max or Mand (n)	RANGE (mm)
Vertical Point	Max(6)	1-4
	Mand(7)	1-4
	Max & Mand(13)	1-4
Horizontal 4mm point	Max(6)	3-5
	Mand(10)	4-8
	Max & Mand(16)	3-8
Horizontal 8mm point	Max(5)	4-8
	Mand(10)	3-4
	Max & Mand(15)	4-8
Total horiz. (4 & 8 mm)	Max(11)	3-5
	Mand(20)	4-8
	Max & Mand(31)	3-8

Table 6-6 Amount Grafted—AVERAGE

Measurement point	Max or Mand (n)	Average (mm)
Vertical Point	Max(6)	2.0
	Mand(7)	2.3
	Max & Mand(13)	2.15
Horizontal 4mm point	Max(6)	3.8
	Mand(10)	6.0
	Max & Mand(16)	5.2
Horizontal 8mm point	Max(5)	4.2
	Mand(10)	5.5
	Max & Mand(15)	5.1
Total horiz. (4&8 mm)	Max(11)	4.0
	Mand(20)	5.8
	Max & Mand(31)	5.1

Table 6-7 Mean Percentage Resorption

Measurement point	Max or Mand (n)	% Resorption
Vertical Point	Max(6)	58%
	Mand(7)	81%
	Max & Mand(13)	70%
Horizontal 4mm point	Max(6)	45%
	Mand(10)	34% w/o IC= 29%
	Max & Mand(16)	38% w/o IC= 36%
Horizontal 8mm point	Max(5)	26%
	Mand(10)	24% w/o IC= 23%
	Max & Mand(15)	24% w/o IC= 24%
Total horiz. (4 & 8 mm)	Max(11)	38%
	Mand(20)	29%w/o IC=27%
	Max & Mand(31)	32%w/o IC=31%

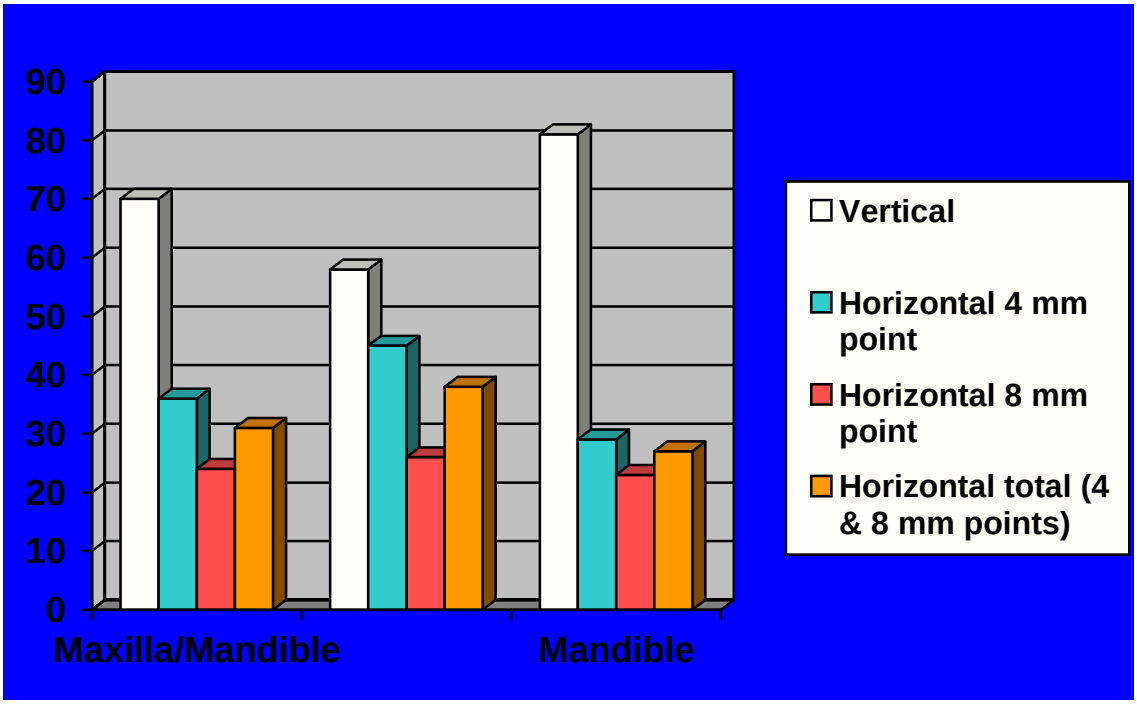


Figure 6-2 Percentage of graft resorption. Infected case (IC) was excluded from this chart.

Statistics for Percentage Graft Resorption

The following slides will show the mean, standard deviation, minimum, maximum, and median percentage graft resorption for whole group, by sites and by gender groups. With and without the IC (infected case).

Table 6-8 Mean and Standard Deviation with Infected Case (IC)
with **IC**

The MEANS Procedure

Variable	N	Mean	Std Dev	Minimum	Maximum	Median
ResorpV_p	13	70.4615385	39.331106	0	100	100
resorpH4_p	16	38.0625	19.7803564	0	75	39
resorpH8_p	15	24.3333333	20.7490677	0	80	25
resorpH4H8_p	16	32.4375	17.1501944	0	70	33

Table 6-9.Means according to Arch with IC
with **IC**
The MEANS Procedure

site=L

Variable	N	Mean	Std Dev	Minimum	Maximum	Median
ResorpV_p	7	80.85714296	28.4043927	25	100	100
resorpH4_p	10	33.9	17.8166589	17	75	27
resorpH8_p	10	23.5	13.8904444	0	43	25
resorpH4H8_p	10	29.2	12.0904002	9	50	29

site=U

Variable	N	Mean	Std Dev	Minimum	Maximum	Median
ResorpV_p	6	58.3333333	49.159604	0	100	75
resorpH4_p	6	45	22.5831796	0	60	50
resorpH8_p	5	26	32.6726185	0	80	25
resorpH4H8_p	6	37.8333333	23.7353464	0	70	41

No statistically significant difference between Upper and Lower arches.

Table 6-10.Means according to Gender with IC
with **IC**

The MEANS Procedure

gender=f

Variable	N	Mean	Std Dev	Minimum	Maximum	Median
ResorpV_p	9	66.6666667	45.0693909	0	100	100
resorpH4_p	12	39.0833333	19.3506323	17	75	33.5
resorpH8_p	12	28.3333333	20.5618063	0	80	25
resorpH4H8_p	12	34.25	16.3935963	9	70	33

gender=m

Variable	N	Mean	Std Dev	Minimum	Maximum	Median
ResorpV_p	4	79	25.1130776	50	100	83
resorpH4_p	4	35	23.8047614	0	50	45
resorpH8_p	3	8.3333333	14.4337567	0	25	0
resorpH4H8_p	4	27	20.800641	0	50	29

No statistically significant difference in % of graft resorption between genders.

Table 6-11 Means and Standard Deviation without IC
without **IC**

The MEANS Procedure

Variable	**N**	**Mean**	**Std Dev**	**Minimum**	**Maximum**	**Median**
ResorpV_p	13	70.4615385	39.331106	0	100	100
resorpH4_p	15	35.6	17.7554821	0	60	38
resorpH8_p	14	24.2857143	21.5314745	0	80	25
resorpH4H8_p	15	31.2666667	17.0774148	0	70	33

Table 6-12.Means according to Arch without IC
without IC

The MEANS Procedure
site=L

Variable	N	Mean	Std Dev	Minimum	Maximum	Median
ResorpV_p	7	80.8571429	28.4043927	0	100	100
resorpH4_p	9	29.3333333	11.0679718	17	50	25
resorpH8_p	9	23.3333333	14.7224319	0	43	25
resorpH4H8_p	9	26.8888889	10.2157286	9	44	25

site=U

Variable	N	Mean	Std Dev	Minimum	Maximum	Median
ResorpV_p	6	58.3333333	49.159604	0	100	75
resorpH4_p	6	45	22.5831796	0	60	50
resorpH8_p	5	26	32.6726185	0	80	25
resorpH4H8_p	6	37.8333333	23.7353464	0	70	41

No statistically significant difference in % of graft resorption between upper and lower arch.

Table 6-13.Means according to Gender without IC
without IC

The MEANS Procedure
gender=f

Variable	N	Mean	Std Dev	Minimum	Maximum	Median
ResorpV_p	9	66.6666667	45.0693909	0	100	100
resorpH4_p	11	35.8181818	16.467047	17	60	29
resorpH8_p	11	28.6363636	21.5372827	0	80	25
resorpH4H8_p	11	32.8181818	16.3879113	9	70	33

Table6-13 continued
gender=m

Variable	N	Mean	Std Dev	Minimum	Maximum	Median
ResorpV_p	4	79	25.1130776	50	100	83
resorpH4_p	4	35	23.8047614	0	50	45
resorpH8_p	3	8.3333333	14.4337567	0	25	0
resorpH4H8_p	4	27	20.800641	0	50	29

No statistically significant difference in % of graft resorption between genders.

Sites group and gender group were compared using parametric T-test and nonparametric Wilcoxon Rank Sum test (because of small sample size and non-normal distribution). There is no statistically significant difference in % resorption between Maxillary and Mandibular groups, and between Female and Male groups. Also, performed was two -way ANOVA (one factor is sites and the other factor is gender) using the raw percent change (parametric way) and using ranks (nonparametric way, again because of small sample size and non-normal distribution). Sites and gender both have no significant effects on the percent changes. Finally, the interaction between sites and gender was also tested in the two-way ANOVA models. There was no statistical significance.

Quality of Bone

The two surgeons were asked to classify the type of bone encountered at implant placement using the Misch bone density classification.

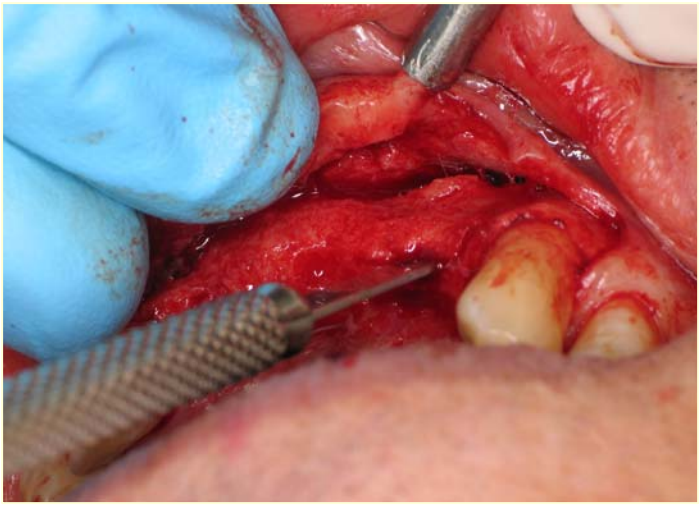
Misch Bone density classification:
- D1, similar to drilling into oak
- D2, similar to pine
- D3, similar to balsa
- D4, similar to Styrofoam

Distribution of bone the different bone densities encountered:
- D1: 3 cases (1 upper, 2 lower)
- D2: 11 (5 upper, 6 lower)
- D3: 2 (2 upper)
- D4: 0 were classified as D4

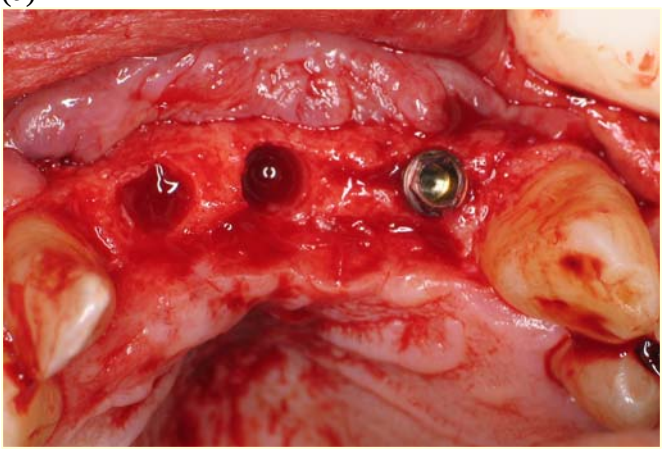
Implant Survival

A total of 25 implants(3i Innovations™, Straumann™, Astra Tech™, & Nobel Biocare™) were placed. Of the implants placed, their diameters were: 1 narrow diameter, 3 wide diameter, and 21 standard diameter. To this date none of the implants paced have failed. 11 have final restorations, the oldest being restored 16 months ago. There were no buccal plate dehiscences at time of placement. Two ridge splits with simultaneous implant placement were performed in maxillary anterior cases to further augment the sites (Figure 10).

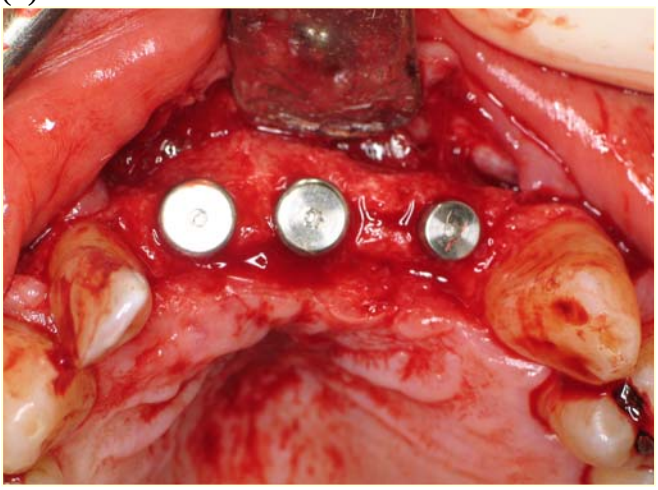
Figure 6-3 Ridge split performed on graft at implant placement. (a) Ridge split procedure was performed on grafted bone at the #10 site. This was an area of membrane exposure during the graft healing. (b) #10 implant placed at site of ridge split procedure. (c) Implant placement. (d) Radiograph of implant placement.



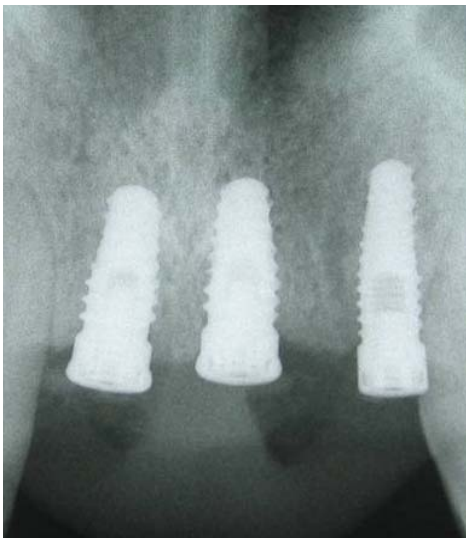
(a)



(b)



(c)



(d)

CHAPTER 7
DISCUSSION

Although this graft material is widely used, to this date there has never been a documented clinical trial study performed using this material to show its clinical efficacy. In the present study, the principle of GBR was applied using demineralized cortical cancellous chips in a thermoplastic matrix in conjunction with a resorbable collagen membrane for the purpose of placing dental implants. There was greater resorption observed in the grafts placed in the maxilla than in the mandible. This has been documented by others i.e. Adell et al, ten Bruggenkate CM, et al. 23,24 It has been speculated that the increase blood supply offered in the maxilla may contribute to the increases seen in graft resorption. Though vertical resorption may have been limited using tenting devices, no such devices were used in this study in order to limit variables and evaluate the raw potential of this graft material. No statistically significant difference was observed between the maxilla and mandible. In all cases with uneventful healing, sufficient bone regeneration was obtained with this procedure to allow for implant placement.

Unlike autogenous block graft materials, this graft material was able to withstand ridge splitting procedures at time of implant placement without consequence. It was demonstrated that DFDBA and cortical cancellous chips in a thermoplastic matrix used as an onlay graft material could minimize or eliminate the need for a donor site. This study shows that when used alone this graft material provides a predictable method for

regenerating vertical bone up to 3 mm, with a mean of 0.54 mm and up to 6 mm of bone horizontally with a mean of 3.66 mm (maxilla= 2.64 mm and mandible= 4.28 mm).

APPENDIX A
STATISTICAL ANALYSIS

BY SITE

The TTEST Procedure

T-Tests

Variable	Method	Variances	DF	t Value	Pvalue
Resorpv_p	Pooled	Equal	11	1.03	0.3242
resorpH4_p	Pooled	Equal	14	-1.09	0.2925
resorpH8_p	Satterthwaite	Unequal	4.74	-0.16	0.8766
resorpH4H8_p	Pooled	Equal	14	-0.97	0.3470

Equality of Variances

Variable	Method	Num DF	Den DF	F Value	Pr > F
Resorpv_p	Folded F	5	6	3.00	0.2142
resorpH4_p	Folded F	5	9	1.61	0.5052
resorpH8_p	Folded F	4	9	5.53	0.0315
resorpH4H8_p	Folded F	5	9	3.85	0.0764

BY gender

The TTEST Procedure

T-Tests

Variable	Method	Variances	DF	t Value	pvalue
Resorpv_p	Pooled	Equal	11	-0.51	0.6233
resorpH4_p	Pooled	Equal	14	0.35	0.7338
resorpH8_p	Pooled	Equal	13	1.57	0.1406
resorpH4H8_p	Pooled	Equal	14	0.72	0.4832

Equality of Variances

Variable	Method	Num DF	Den DF	F Value	Pr > F
Resorpv_p	Folded F	8	3	3.22	0.3651

resorpH4_p	Folded F	3	11	1.51	0.5311
resorpH8_p	Folded F	11	2	2.03	0.7524
resorpH4H8_p	Folded F	3	11	1.61	0.4866

by site

5

13:32 Sunday, March 19, 2006

The NPAR1WAY Procedure

Wilcoxon Scores (Rank Sums) for Variable Resorpv_p
Classified by Variable site

Two-Sided Pr > |Z| pvalue= 0.4973

Wilcoxon Scores (Rank Sums) for Variable resorpH4_p
Classified by Variable site

Two-Sided Pr > |Z| | pvalue= 0.1750

Wilcoxon Scores (Rank Sums) for Variable resorpH8_p
Classified by Variable site

Two-Sided Pr > |Z| | pvalue= 0.6551

Wilcoxon Scores (Rank Sums) for Variable resorpH4H8_p
Classified by Variable site

Two-Sided Pr > |Z| | pvalue= 0.3157

By gender

9

Wilcoxon Scores (Rank Sums) for Variable Resorpv_p
Classified by Variable gender

Two-Sided Pr > |Z| pvalue= 0.9344

Wilcoxon Scores (Rank Sums) for Variable resorpH4_p
Classified by Variable gender

Two-Sided Pr > |Z| pvalue= 0.9520

Wilcoxon Scores (Rank Sums) for Variable resorpH8_p
Classified by Variable gender

Two-Sided Pr > |Z| pvalue= 0.1289

Wilcoxon Scores (Rank Sums) for Variable resorpH4H8_p
Classified by Variable gender

Two-Sided Pr > |Z| pvalue= 0.7191

The TTEST Procedure

By site

T-Tests

Variable	Method	Variances	DF	t Value	Pr > |t|
Resorpv_p	Pooled	Equal	11	1.03	0.3242
resorpH4_p	Pooled	Equal	13	-1.80	0.0945
resorpH8_p	Pooled	Equal	12	-0.21	0.8343
resorpH4H8_p	Satterthwaite	Unequal	6.25	-1.07	0.3260

Equality of Variances

Variable	Method	Num DF	Den DF	F Value	Pr > F
Resorpv_p	Folded F	5	6	3.00	0.2142
resorpH4_p	Folded F	5	8	4.16	0.0736
resorpH8_p	Folded F	4	8	4.93	0.0535
resorpH4H8_p	Folded F	5	8	5.40	0.0364

The TTEST Procedure

By gender

T-Tests

Variable	Method	Variances	DF	t Value	Pr > |t|
Resorpv_p	Pooled	Equal	11	-0.51	0.6233
resorpH4_p	Pooled	Equal	13	0.08	0.9405
resorpH8_p	Pooled	Equal	12	1.52	0.1547
resorpH4H8_p	Pooled	Equal	13	0.57	0.5789

Equality of Variances

Variable	Method	Num DF	Den DF	F Value	Pr > F
Resorpv_p	Folded F	8	3	3.22	0.3651
resorpH4_p	Folded F	3	10	2.09	0.3305
resorpH8_p	Folded F	10	2	2.23	0.6991
resorpH4H8_p	Folded F	3	10	1.61	0.4964

Wilcoxon Scores (Rank Sums) for Variable Resorpv_p
Classified by Variable site
Two-Sided Pr > |Z| 0.4973

Wilcoxon Scores (Rank Sums) for Variable resorpH4_p
Classified by Variable site
Two-Sided Pr > |Z| 0.0771

Wilcoxon Scores (Rank Sums) for Variable resorpH8_p
Classified by Variable site
Two-Sided Pr > |Z| 0.6804

Wilcoxon Scores (Rank Sums) for Variable resorpH4H8_p
Classified by Variable site
Two-Sided Pr > |Z| 0.2123

Wilcoxon Scores (Rank Sums) for Variable Resorpv_p
Classified by Variable gender
Two-Sided Pr > |Z| 0.9344

Wilcoxon Scores (Rank Sums) for Variable resorpH4_p
Classified by Variable gender
Two-Sided Pr > |Z| 0.9483

Wilcoxon Scores (Rank Sums) for Variable resorpH8_p
Classified by Variable gender
Two-Sided Pr > |Z| 0.1432

Wilcoxon Scores (Rank Sums) for Variable resorpH4H8_p
Classified by Variable gender
Two-Sided Pr > |Z| 0.8463

APPENDIX B
RAW DATA

patient	site	gender	Grafted V	Resorption V	%Resorption V	grafted H4	resorption H4	%resorp H4	grafted H8	resorp H8	%resorp H8	grafted H4&H8	resorp H4&H8	%resorp H4&H8
RW	L	m	3	2	66	5	2	40	4	1	25	9	3	33
AJ-1	U	f	2	2	100	5	3	60	4	1	25	9	4	44
AJ-2	L	f	4	1	25	8	2	25	8	2	25	16	4	25
AJ-3	L	f	1	1	100	4	1	25	4	1	25	8	2	25
LR	L	f	0	0	0	6	1	17	5	0	0	11	1	9
DH-1	L	f	0	0	0	8	4	50	8	3	38	16	7	44
DH-2	L	f	2	2	100	5	1	20	7	3	43	12	4	33
DB	U	m	2	1	50	4	2	50	4	0	0	8	2	25
DD-1	L	f	4	3	75	5	1	20	4	1	25	9	2	22
DD-2	L	f	1	1	100	8	3	38	7	2	29	15	5	33
PC	U	f	1	1	0	5	3	60	5	4	80	10	7	70
JR	U	m	2	2	100	4	2	50	na	na	na	4	2	50
AS-1	L	f	1	1	100	7	2	29	4	0	0	11	2	18
AS-2 IC	L	f	0	0	0	4	3	75	4	1	25	8	4	50
AH	U	f	1	0	0	4	2	50	4	1	25	8	3	38
DM	U	m	4	4	100	3	0	0	4	0	0	7	0	0

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BIOGRAPHICAL SKETCH

Dr. Angel R Santiago attended the University of Central Florida where he studied molecular biology and microbiology. He graduated from Nova Southeastern University, College of Dental Medicine, in May 2003. At this time Angel Santiago is attending the University of Florida where he is completing his post-graduate residency in periodontics.