PORCINE COLLAGEN MATRIX WITH AND WITHOUT ENAMEL MATRIX DERIVATIVE FOR THE TREATMENT OF GINGIVAL RECESSION DEFECTS

by

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in partial fulfillment of the requirements for the degree of
Master of Science
in Oral Biology

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Naval Postgraduate Dental School

Uniformed Services University of the Health Sciences

Bethesda, Maryland

CERTIFICATE OF APPROVAL

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MASTER'S THESIS

_____

This is to certify that the Master's thesis of

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June 2019

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2019

ABSTRACT

PORCINE COLLAGEN MATRIX WITH AND WITHOUT ENAMEL MATRIX DERIVATIVE FOR THE TREATMENT OF GINGIVAL RECESSION DEFECTS

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Introduction: Gingival recession is a common occurrence with an estimated 61.3 million adults over the age of 30 having at least one millimeter of recession. Recession defects are commonly treated with connective tissues grafts (CTG). However, these autogenous grafts require a second surgical site and are limited by anatomic factors. Collagen matrix (CM) is a xenogeneic material that has shown comparable results to CTG when utilized for treatment of gingival recession. Enamel matrix derivative (EMD) has been shown to enhance root coverage procedures, especially when used in conjunction with coronally advanced flaps (CAF).

Purpose: This prospective, blinded, randomized, split-mouth study compared the effectiveness of a porcine collagen matrix (CM) and coronally advanced flap (CAF) with or without the addition of enamel matrix derivative (EMD) in the treatment of recession defects.

Methods: Thirty subjects with paired, similarly-sized Miller class I, II, or predictable class III recession defects on single-rooted teeth will be compared. For each subject, qualified defects will vary no more than 2mm in size. One defect will be randomly assigned as the experimental group using CM + EMD + CAF, and the other as the control group using only CM + CAF. Surgical outcomes will be assessed using the following clinical measurements: probing depth (PD), clinical attachment level (CAL), gingival recession (GR), and width of keratinized tissue (KT). Percent root coverage (RC) will be calculated. The data will be obtained by calibrated, board-certified periodontists at baseline, 3 months, and 6 months post-surgery for statistical comparison.

Results: To date, two subjects have been enrolled and treated. Initial 3-month data revealed an average of 60% root coverage for the experimental group, and 66% for the control group.

Conclusion: Research is ongoing and enrollment will continue until the target of 30 subjects is reached.

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LIST OF ABBREVIATIONS

AG - Attached Gingiva

BID - Twice per day

CAF - Coronally Advanced Flap

CAL - Clinical Attachment Level

CEJ - Cemento-Enamel Junction

CM – Collagen Matrix

CTG - Connective Tissue Graft

EDTA - Ethylenediaminetetraacetic Acid

EMD - Enamel Matrix Derivative

FDA - Food and Drug Administration

FG – Free Gingiva

FGM - Free Gingival Margin

GR – Gingival Recession

KG - Keratinized Gingiva

KT- Width of Keratinized Tissue

mg - Milligram

MGJ - Mucogingival Junction

PD - Probing Depth

PO – Taken by Mouth

RC – Percent Root Coverage

qXh - Every X hours where X is an integer

S-BOP - Stent to Base of Pocket

S-CEJ - Stent to CEJ

S-FGM - Stent to FGM

S-MGJ - Stent to MGJ

SNOSE - Sequentially Numbered Opaque Sealed Envelope

TBSP - Tablespoon

CHAPTER I: INTRODUCTION AND REVIEW OF LITERATURE

The hard tissue structures of a tooth consist of enamel, dentin, and cementum. Enamel makes up the outer white shell and is commonly called the crown. Dentin makes up the inner core of the both the crown and tooth root. A thin layer of cementum covers the dentin that comprises the root. The crown is distinguished from the root at the cemento-enamel junction (CEJ) where the enamel meets the cementum. The term gingiva describes areas of keratinized epithelium that surround teeth. The gingiva is continuous with the mucosa of the oral cavity at the mucogingival junction (MGJ) and with the periodontal ligament in the gingival sulcus. The keratinized gingiva (KG) is divided into two parts, the free and attached gingiva (Figure 1). The portion of the gingiva that is bound to the bone and secured in place is termed the attached gingiva (AG). In contrast, the unbound gingival component is termed the free gingiva (FG). The most coronal portion of the free gingiva that ends on the tooth is termed the free gingival margin (FGM).[1]

Gingival recession refers to the migration of the gingival margin to a point apical to the CEJ resulting in visual root exposure.[1] Gingival recession is a common occurrence, with 61.3 million adults over the age of thirty having at least one millimeter of recession. The prevalence of gingival recession in adults 30-39 years of age is 37.8% on 8.6% of teeth, while adults 80-90 years old display a prevalence of 90.4% on 56.3% of teeth.[2] With increasing age, gingival recession has been shown to increase in prevalence and severity. Race and gender comparisons revealed the extent of recession to be significantly higher in males than females, and higher in African Americans than

Caucasians.[2] Factors that contribute to gingival recession include: periodontal disease, traumatic tooth brushing techniques, anatomical factors, ill-fitting prostheses, and tooth malposition.[2-5] Additional studies have shown that smokeless tobacco use can also promote gingival recession.[6,7]

Despite being a common occurrence, the mere presence of gingival recession does not necessitate surgical intervention. Nevertheless, there are instances when a surgical solution is necessary. Such instances include the need to address the patient's esthetic concerns, increase the width of KG for resilience and stability, and eliminate dentinal sensitivity. Gingival recession can also produce uneven gingival margins that negatively affect an individual's self-image.[8] Studies have shown the width of KG to be an important factor in maintaining gingival health. Areas lacking KG have been associated with inflammation and progression of gingival recession.[3,9,10] Dentinal sensitivity, caused by exposed root dentin, can trigger a pain response to normal stimuli such as cold, heat, and touch. Surgical procedures to correct soft tissue recession can lead to a decrease in dentinal sensitivity of the associated tooth.[11] Patients may be at greater risk for developing root caries with gingival recession due to exposed dentin being less mineralized than enamel.[12] Surgical root coverage procedures may be an effective way to reduce root caries by covering the exposed root surface with connective tissue or an epithelial attachment.[13]

Multiple classification systems for gingival recession exist. One of the most widely used systems was developed in 1985 by Dr. P.D. Miller. His system not only describes the extent of the recession defect, but also predicts the success of coverage that can be achieved with surgery. Factors that influence success include the level of

interproximal bone and associated soft tissue, as well as tooth position within the dental arch. According to the Miller classification system, a Class I recession defect has no interproximal bone or soft tissue loss, and the margin of tissue recession does not extend to the MGJ. In a Class II recession defect, there is no interproximal bone or soft tissue loss, but the margin of tissue recession extends to or beyond the MGJ. Both Class I and Class II recession defects are predicted to have up to 100% root coverage with surgical treatment. A Class III recession defect is noted when a tooth has interproximal bone loss or malpositioning, and only partial root coverage is anticipated following surgery. However, in teeth with minimal interproximal bone loss (<15%) and no malposition, the recession defect may be considered "predictable" with a high percentage of root coverage expected. In a Class IV recession defect, there is bone or soft tissue loss in the interproximal area and/or tooth malposition that is so severe that root coverage is not expected.[14]

While many surgical techniques exist to correct gingival recession, the sub-epithelial connective tissue graft (CTG) is well-studied and commonly employed in periodontal practice. In this technique, a graft is harvested from the hard palate, where part of the underlying connective tissue is removed, leaving the overlying palatal epithelium intact. The connective tissue is then transferred to the area of recession for coverage of the exposed root.[15] Through biologic signaling, connective tissue determines the physical characteristics of the overlying surface epithelium, and hence, connective tissue harvested from keratinized tissue will result in the expression of similar tissue phenotype when transplanted to the recipient site. Conversely, connective tissue harvested from non-keratinized epithelium will express non-keratinized epithelium when

transplanted.[16] The entire hard palate is covered with keratinized, attached tissue that often allows for a suitably-sized graft to be harvested. Upon healing, the CTG has been shown to create a new connective tissue attachment to previously diseased root surfaces.[17]

In the decades since the CTG technique was first described, a multitude of studies have proposed modifications to the original approach, resulting in a similar decrease in recession with concomitant increase in clinical attachment and keratinized tissue.[18-21] In 2009, Bittencourt combined the use of a CTG with a coronally advanced flap (CAF) in Miller class I recession defects, yielding an average root coverage of 96.8% that was stable over 6-30 months.[22] Buti completed a meta-analysis of root coverage procedures and found that CTG with CAF not only performed the best, but might be considered the "gold standard" for root coverage.[23] Additionally, systematic reviews and meta-analyses have demonstrated the equivalence or superiority of CTGs compared to other techniques.[22-35]

Despite numerous studies showing success with using CTGs to treat recession, there are some limitations with this technique. First, a CTG requires a second surgical site for graft harvest, resulting in increased length of surgery and risk for complications such as infection, nerve damage, bleeding, and pain. Increased length of surgical procedures has been highly correlated with increased pain and swelling post-operatively.[36,37] Second, the anatomy of the patient's palate limits the amount of tissue that may be harvested in a single procedure. In patients with multiple recession defects, the presence of limited tissue volume may necessitate additional surgeries and increase total treatment time to correct the recession.[38]

The use of a collagen matrix (CM) is FDA-approved for correction of gingival recession and augmentation of KG. These xenogeneic matrices can be derived from porcine or bovine sources. Their main advantage as an alternative to CTGs is the elimination of the need for a second surgical site. CMs also have unlimited availability, while CTGs are limited by the amount of tissue that can be harvested from a particular patient. In 2010, Osteohealth Inc. introduced Mucograft®, a bi-layered, type I/III collagen grafting alternative. Mucograft® derives from veterinary-certified pig tendons. Sterilized by gamma irradiation, Mucograft® displays low antigenicity and excellent biocompatibility. Ranging from 2.5 to 5mm in thickness, its bi-layered structure is composed of a thin outer layer and a thick, porous inner layer. The compact outer layer allows for better handling characteristics during placement and suturing, while the spongy inner layer encourages cellular infiltration and vascular in-growth.[39]

Porcine collagen matrices have demonstrated similar efficacy in treating recession when compared to connective tissue grafts. Cardaropoli compared a porcine CM + CAF to CTG + CAF for the treatment of recession, and reported similar average root coverage ranging from 94.32% (CM) to 96.97% (CTG).[40] Several other studies have demonstrated the efficacy and safety of this material.[41-48] The ability to treat multiple recession defects and have comparable outcomes to CTG allows CM to be considered a viable alternative for treating gingival recession defects.

Enamel matrix derivative (EMD), commercially available under the brand name Emdogain®, is an amelogenin derivative of embryonic porcine enamel and is FDA-approved to treat recession defects.[49] Amelogenins comprise the majority of the proteins in EMD, while others such as tuftelin, ameloblastin and amelin comprise the remainder.

EMD is thought to mimic the role of proteins necessary for cementogenesis and root development. The biologic properties of EMD may promote more rapid healing of the soft tissue and stimulate angiogenesis.[49]

EMD has undergone exhaustive research demonstrating its safety and efficacy. Research outcomes consistently demonstrate EMD's ability to increase clinical attachment levels, promote root coverage, and reduce probing depths.[50-52] In 2003, McGuire compared EMD + CAF to CTG + CAF, and found that the average root coverage percentage at 12 months was 95.1% and 93.8%, respectively. Additionally, when comparing sites that had complete root coverage, the EMD + CAF group was superior. Complete root coverage was obtained in 89.5% of the EMD + CAF group compared to 79% for the CTG + CAF group.[53,54]

EMD has been shown to enhance the results of root coverage procedures. Henriques published a split-mouth study comparing CTG + CAF with or without EMD. concluding that the addition of EMD to CTG + CAF provided an increase in clinical attachment level (CAL) and a decrease in probing depth.[55] In a meta-analysis by Cheng in 2015, EMD was found to reduce probing depth and increase keratinized tissue width.[52]

Evidence has demonstrated that CM and CTG have comparable results when treating gingival recession, and EMD has been shown to have additional benefit when used with CTG or alone.[44,53,54] Therefore, it may be surmised that the addition of EMD may result in improved outcomes over CM alone. To date, there have been no split-mouth randomized controlled trials that compare CM + CAF to CM + EMD + CAF. The purpose of this study is to determine if the addition of EMD results in increased root coverage compared to CM alone in patients with Miller Class I, II, or predictable Class

III recession defects. Additionally, changes in clinical parameters, including probing depth (PD), clinical attachment level (CAL), and width of keratinized tissue (KT), will be assessed and compared between the control and treatment groups.

CHAPTER II: MATERIALS AND METHODS

Thirty subjects will be consented and enrolled to obtain a minimum of 24 subjects with matching Miller Class I, II or III recession defects (Appendix A). Corrective surgical treatment will be offered in accordance with accepted indications for root coverage procedures. A study investigator will initiate the patient education and informed consent process as described below.

Initial Phase

1. Subject is referred to the Naval Postgraduate Dental School (NPDS), Periodontics Department for evaluation.
2. Staff member provides study brief during screening exam.
3. Principal or associate investigators notified and introduced to subject.
4. Patient undergoes a periodontal evaluation to determine if he/she meets inclusion criteria for study. Patients meeting study criteria will be provided with an informational handout (Appendix F).
5. Full written disclosure of the study protocol, including the option to receive any necessary treatment without being part of the study, is presented to the subject. All of the subject's questions and concerns are addressed.
6. If the subject is willing to participate, informed consent is obtained and HIPAA forms are completed. If the subject is uncertain about participation, the subject will be permitted to take all forms home to review and decide at a later date.
7. Once consent is obtained, specific recession defects will be identified and the subject will be given a coded subject identification number by the principal investigator (PI).

Surgical Phase: The surgical provider will be a faculty member or resident of NPDS Periodontics Department. All surgeries will follow the steps described below.

1. Baseline probing measurements (GR, PD, CAL and width of KT) will be collected by a blinded associate investigator.
2. Both surgical sites will undergo identical procedures simultaneously, with the exception of adding EMD to the test group. The order and site receiving EMD will be determined by Sequentially Numbered, Opaque, Sealed Envelope (SNOSE) opened by the surgeon immediately prior to surgery. The principal investigator will record which tooth received the CM + CAF and which tooth received CM + EMD + CAF on the Master List:
    - **a.** Administration of oral anxiolysis or intravenous moderate sedation will be determined by the surgical provider after patient assessment.
    - **b.** Patient will be anesthetized using local anesthetic.
    - **c.** The exposed portion of the tooth root with recession will be prepared and cleaned in the same manner on both sides of the mouth.
    - **d.** A recipient pouch at the treatment site will be created via an intra-sulcular incision with release of a combination split-full-split flap.
    - **e.** All exposed root surfaces being treated will be conditioned using 24% EDTA for 2 minutes, then irrigated copiously with sterile saline.
    - **f.** For the experimental subjects only, EMD will be applied to the entire exposed root surface.

g. Mucograft® will be cut to the appropriate size to cover the defect. The Mucograft® will be placed directly onto the root in control sites. In experimental sites, Mucograft® will be placed over the EMD-treated root. The graft material will be sutured into place using a resorbable suture material of the provider's choice.

h. The flap will be coronally advanced to cover the graft and secured to the de-epithelialized papilla at or slightly above the level of the CEJ using a non-resorbable suture material of the provider's choice.

i. The subjects will be asked to avoid brushing or flossing in the grafted sites for 6 weeks following surgery to allow for undisturbed healing of the graft. Subjects will also be asked to avoid strenuous activity for 72 hours.

3. All subjects will receive written post-operative instructions (Appendix C) and be prescribed the following post-operative medication regimen:

a. 0.12% chlorhexidine gluconate: Rinse and expectorate BID after breakfast and before bedtime with 1 TBSP for 30 seconds as a replacement for brushing to inhibit plaque formation in the surgical site.

b. Pain medication consisting of any of the following as determined by the surgical provider:

i. Ibuprofen 800 mg: Take 1 tab PO q6-8h for moderate pain

ii. Hydrocodone/Acetaminophen 5/325 mg: Take 1-2 tabs PO q6h as needed for severe /break-through pain

iii. Acetaminophen 325 mg: Take 1-2 tabs PO q4h for moderate pain

Post-Operative Phase: Subjects will be recalled at 1, 2, 4, and 6 weeks to monitor post-operative healing and remove plaque and debris at the surgical site.

1. Sutures will be removed no earlier than 2 weeks after surgery.
2. After 6 weeks, subjects will be instructed to resume normal hygiene using a soft toothbrush.
3. Subjects will be recalled at the 3 and 6-month mark (+/- 2 weeks) following surgery to continue healing assessment, plaque removal, oral hygiene reinforcement and research data collection. Three and 6-month probing measurements (GR, PD, CAL and width of KT) will be collected by a study investigator. Additionally, 3 and 6-month impressions for stone models will be taken by study investigators. After 6 months of post-operative care, the subject's participation in the study concludes, and he/she will be referred to their primary dental provider for continuation of routine care.

CHAPTER III: RESULTS

This research protocol has been approved by WRNMMC IRB. To date, two subjects have been enrolled and treated. The mean baseline and 3-month data are presented in Table 1. Both the CM + CAF (control) and CM + EMD + CAF (test) groups showed improvement in GR, CAL, KT, and RC. The control group saw a slight increase in PD at 3 months on average. Despite the raw data showing a trend for improvement in clinical parameters, providers should be cautious when interpreting this data. This study is ongoing with 2 subjects currently enrolled, and no statistical analysis is possible at this early stage.

TABLE 1:
Baseline and 3-month data

	Baseline CM+EMD+CAF	Baseline CM+CAF	3 Months CM+EMD+CAF	3 Months CM+CAF
Gingival Recession (mm)	3	3.25	1	1
Probing Depth (mm)	2	1	1	1.5
Clinical Attachment Level (mm)	5	4.25	2	2.5
Width of Keratinized Tissue (mm)	1	2	3.25	3.5
Root Coverage (%)			60	66.5

CHAPTER IV: DISCUSSION

Two subjects in the study were treated with a split-full-split technique as described in previous studies.[42,56,57] While it is impossible to complete statistical analysis at this point, there were clear differences in clinical parameters for the two subjects. The first subject had both mandibular first premolars treated, and the second subject had both maxillary canines treated. In the first subject, an average between the control and test showed only 26% root coverage at 3 months. In contrast, the second patient had 100% root coverage at 3 months. A likely explanation for this difference is that the premolars treated in the first subject were adjacent to dental implants. This likely led to decreased interproximal bone and soft tissue levels on the distal aspect of the treated teeth. Factors related to the previous implant surgery and patient compliance could have affected the results.

Recruiting subjects with bilateral recession defects in single-rooted teeth has proven difficult in this patient population. Patients typically present with either a single isolated recession defect or multiple recession defects. For ethical reasons, it is inappropriate to ignore recession adjacent to sites considered ideal for inclusion in this study.

Enrollment was also delayed by 6 months because EMD was commercially unavailable due to an FDA-mandated recall. The recall was not due to product safety concerns, but due to unapproved changes in stated shelf life.

A possible means to improve subject recruitment is to actively seek referrals from other Department of Defense dental clinics in the region. Modification of the protocol to

include multi-rooted teeth and/or eliminate the requirement for bilaterally paired defects could also improve enrollment. While the highest level of comparative evidence would derive from the bilaterally paired defect design as currently written, valued clinical information could also be gained by comparing CM + CAF to CM + EMD + CAF outside of the split-mouth environment.

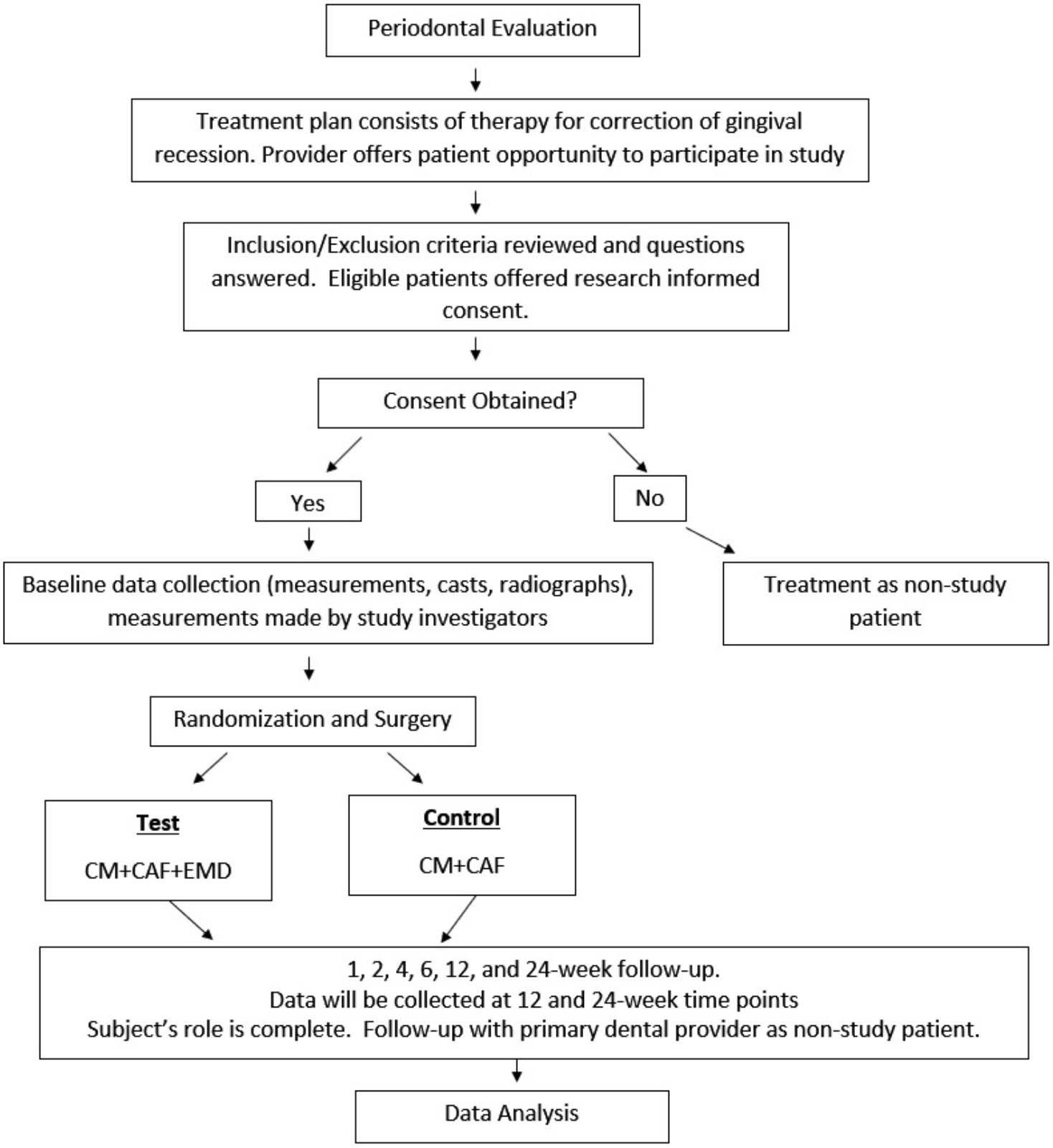
Lastly, since this research protocol was approved by WRNMMC IRB, the Cairo classification system for recession has been supported by the 2017 World Workshop on the Classification of Periodontal and Peri-Implant Diseases and Conditions. While the Miller scheme is unlikely to become obsolete at the clinical level, future research designs may choose the Cairo recession classification in deference to the consensus publication by the American Academy of Periodontology. With the future in mind, a modification to the current research protocol to include the Cairo classification may be warranted.

CHAPTER V: CONCLUSION

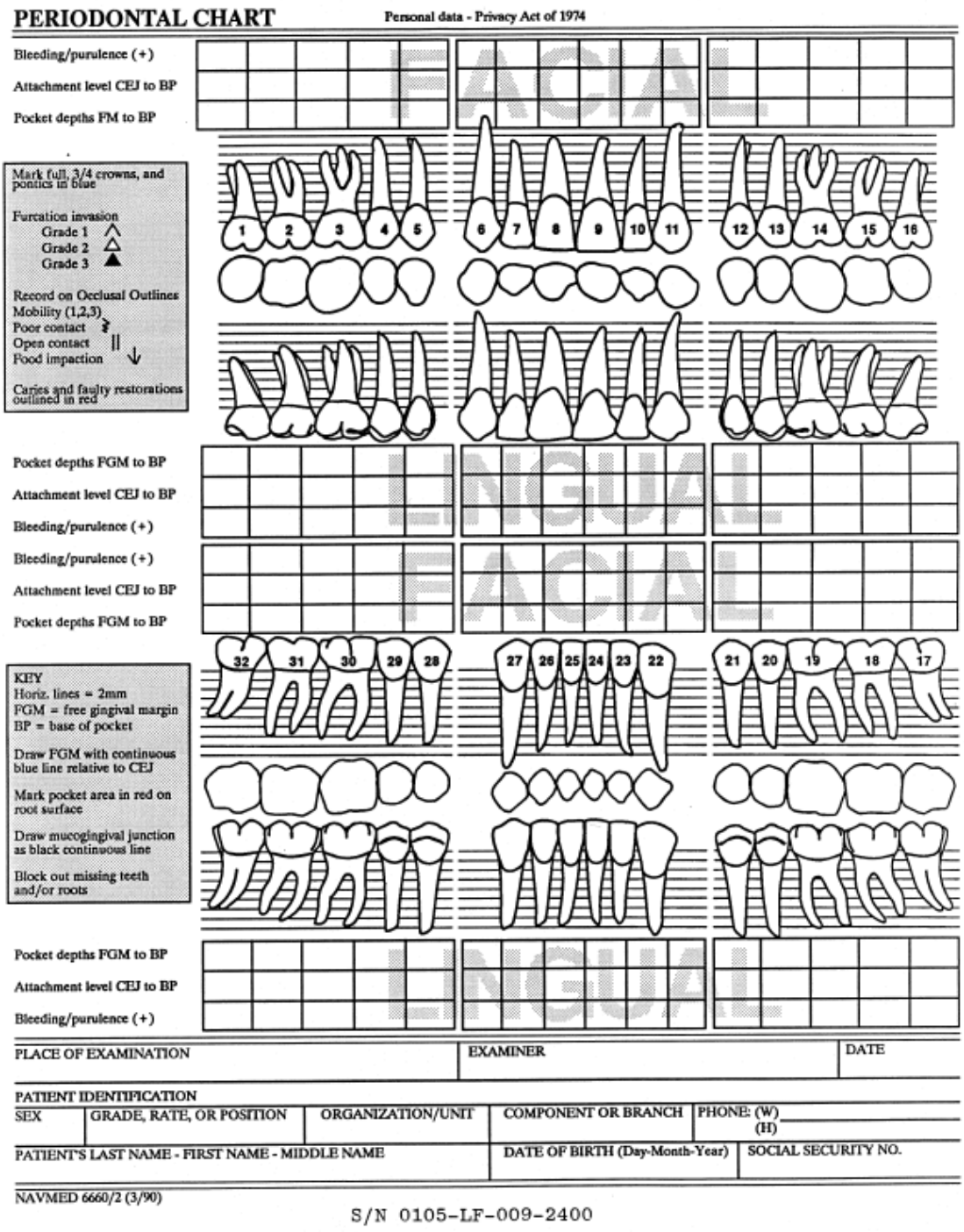
Gingival recession is a common occurrence and there exist multiple methods for treatment. The CTG has long been considered the standard of care or gingival recession, and has been extensively studied.[23] However, the CTG requires a second surgical site and is limited by patient anatomy. Xenogeneic alternatives to CTG have been developed that do not require a second surgical site and are not limited in amount that can be acquired. CM has been shown to have comparable results to CTG, and EMD has been shown to have added benefit when combined with CTG. The purpose of this, double-blinded, randomized, split-mouth study is to compare the effectiveness of a porcine collagen matrix and coronally advanced flap with or without the addition of EMD in the treatment of recession defects.

The author theorizes that in Miller Class 1, 2, and predictable 3 recession defects, there will be added improvement in clinical parameters. Whether these improvements will be statistically or clinically significant is yet to be determined. In a comparable study design, Sangiorgio found that CM + CAF obtained 88.7% root coverage compared to 91.6% for CM + CAF + EMD. Additionally, the author declared that both groups had an increase in keratinized gingiva compared to CAF alone.[56] Given this recent report showing the added benefit of EMD to be a meager 2.9% in additional root coverage, future studies should focus on improving the accuracy of clinical data used to calculate root coverage outcomes.

APPENDIX A: STUDY DESIGN FLOW DIAGRAM



APPENDIX B: COMPREHENSIVE PERIODONTAL CHARTING FORM



APPENDIX C: NPDS PERIODONTICS DEPARTMENT POST OPERATIVE INSTRUCTIONS

PERIODONTICS DEPARTMENT
NAVAL POSTGRADUATE DENTAL SCHOOL
Bethesda, Maryland

For best healing and a minimum of complications, please read and follow these instructions carefully

---

You may have been given one or more of these medications:

PAIN MEDICATIONS:	_____ Motrin 800 mg:	*1 tablet every 8 hours.* Do not double up on dosage.
	_____ Norco 5/325 mg:	*1 tablet every 6 hours for pain control.* It can be taken in addition to ibuprofen. This medicine can make you drowsy. Therefore, do not drive or operate machinery while taking this drug. Additionally, do not take with alcoholic beverages; the alcohol will make you sleepier, but will not decrease your comfort.
ANTIBIOTICS:	_____ Doxycycline 100 mg:	*2 tablets the day of surgery, then 1 tablet every day for 30 days.*
	_____ Amoxicillin 500 mg:	*1 tablet four times a day for 7 to 10 days.*
	_____ Clindamycin 300 mg:	*1 tablet four times a day for 7 to 10 days.*
RINSES:	_____ Peridex (Perioguard):	*1 bottle, rinse twice-a-day as directed on the bottle, starting the day following surgery.* Do not brush or floss at the surgical site unless instructed to do so.
ANTI-INFLAMMATION:	_____ Medrol Dose Pack:	Take as directed on the package, starting today. Be sure and take the full first row of tablets (first six tablets) today.

The following are a list of post-operative considerations during healing:

BLEEDING:	There may be slight bleeding from the surgical for 1-2 days after surgery. Your saliva may appear slightly reddish. This is common. If you notice an increase in bleeding please contact us.
SUTURES/STITCHES:	You may have sutures placed in your mouth. They may have to be removed in the future. Please leave the sutures alone as much as possible. Early removal or the loss of sutures may impair healing.
DRESSINGS:	There may be a gummy type of dressing or pack over the surgical area. It is there for your comfort. If it falls out before your first post-operative appointment and you are comfortable, it is fine to leave it out. If the surgical site is uncomfortable and you would like the dressing replaced please contact me.
DIET:	It is very important to maintain a soft diet for at least a week. Chew as much as possible on the side opposite the surgery. This is not the time to start a diet. Please maintain your caloric and fluid intake as at pre-surgical levels. You will not heal well if you are dehydrated or undernourished. Please do not drink using a straw.
ORAL HYGIENE:	It is very important not to brush or floss the surgical site until given express instructions. Normal brushing and flossing procedures can traumatize the tissue and impair healing. You may brush and floss those areas not affected by the surgery. To keep bacteria under control a prescription mouth rinse has been written for you. Initially, use the mouthwash as a rinse. Later you may be instructed to use a cotton-tipped applicator, dipped in the mouthwash, to swab along the gum line of the surgery site. Use a capful (15ml) of the mouthwash twice a day, morning and bedtime, after brushing/flossing your non-surgically treated teeth. You may notice a mild tooth staining as a result of the mouthwash. This is not permanent; the stain will be removed with scaling/polishing at your follow-up appointments. Please do not use a Water-Pik or other irrigator unless instructed to do so.
PHYSICAL ACTIVITY:	Avoid strenuous physical activity (to include running and heavy lifting) for 72 hours. Additionally, no vigorous spitting, rinsing, or speaking (yelling). Forceful movements at the site of surgery will negatively affect healing.
SWELLING:	You may experience some swelling. This is common and usually peaks at 2-3 days after surgery. Thereafter you should expect to see a return to normal. To decrease swelling you can apply ice to the site for the first 3-4 hours after surgery. Please call if the swelling appears to increase after the third day, or if you are concerned.
SMOKING	Smoking is deleterious to healing. We advise you to stop smoking for as long as possible after surgery. Stopping smoking will improve potential healing and also improve your overall periodontal health.
FOR SINUS LIFT SURGERY PROCEDURES	You may also have received nasal decongestant tablets and spray. Please use these medications as directed on the package. In addition, avoid blowing your nose. If you need to sneeze, please sneeze with your mouth open. Please inform your doctor if you develop sinus congestion that is not minimized with your medications or if you notice any bleeding or discharge from your nose.

If you have any problems or questions, please do not hesitate to call me at 301-295-0077. If there is an emergency you may contact your doctor at the following number: _____

Your follow up appointment is scheduled for: _____ _____

NPDS , Bethesda

APPENDIX D: DATA COLLECTION SHEET

Data Collection Sheet

Clinical / Digital
(circle one)

Subject Identification #	
Date	
Provider	

Baseline Pre-Operative Measurements	**Tooth#**	**Tooth#**
Gingival Recession (GR)* (Cemento-enamel Junction to Free Gingival Margin)		
Probing Depth (PD) (Free Gingival Margin to Base of Pocket)		
Clinical Attachment Level (CAL) (Cemento-enamel Junction to Base of Pocket)		
Width of Keratinized Tissue (KT) (Free Gingival Margin to Mucogingival Junction)		

3 Month Post-Operative Measurements	**Tooth#**	**Tooth#**
Gingival Recession (GR)* (Cemento-enamel Junction to Free Gingival Margin)		
Probing Depth (PD) (Free Gingival Margin to Base of Pocket)		
Clinical Attachment Level (CAL) (Cemento-enamel Junction to Base of Pocket)		
Width of Keratinized Tissue (KT) (Free Gingival Margin to Mucogingival Junction)		
Percent Root Coverage (%RC) (3 mo. post-op GR - pre-operative GR) / pre-operative GR)		
Change in Tissue Thickness* (STL file comparison of 3 month cast to baseline)		

6 Month Post-Op Measurements	Tooth#	Tooth#
Gingival Recession (GR)* (Cemento-enamel Junction to Free Gingival Margin)		
Probing Depth (PD) (Free Gingival Margin to Base of Pocket)		
Clinical Attachment Level (CAL) (Cemento-enamel Junction to Base of Pocket)		
Width of Keratinized Tissue (KT) (Free Gingival Margin to Mucogingival Junction)		
Percent Root Coverage (%RC) (6 mo. post-op GR - pre-operative GR) / pre-operative GR)		
Change in Tissue Thickness* (STL file comparison of 6 month cast to baseline)		

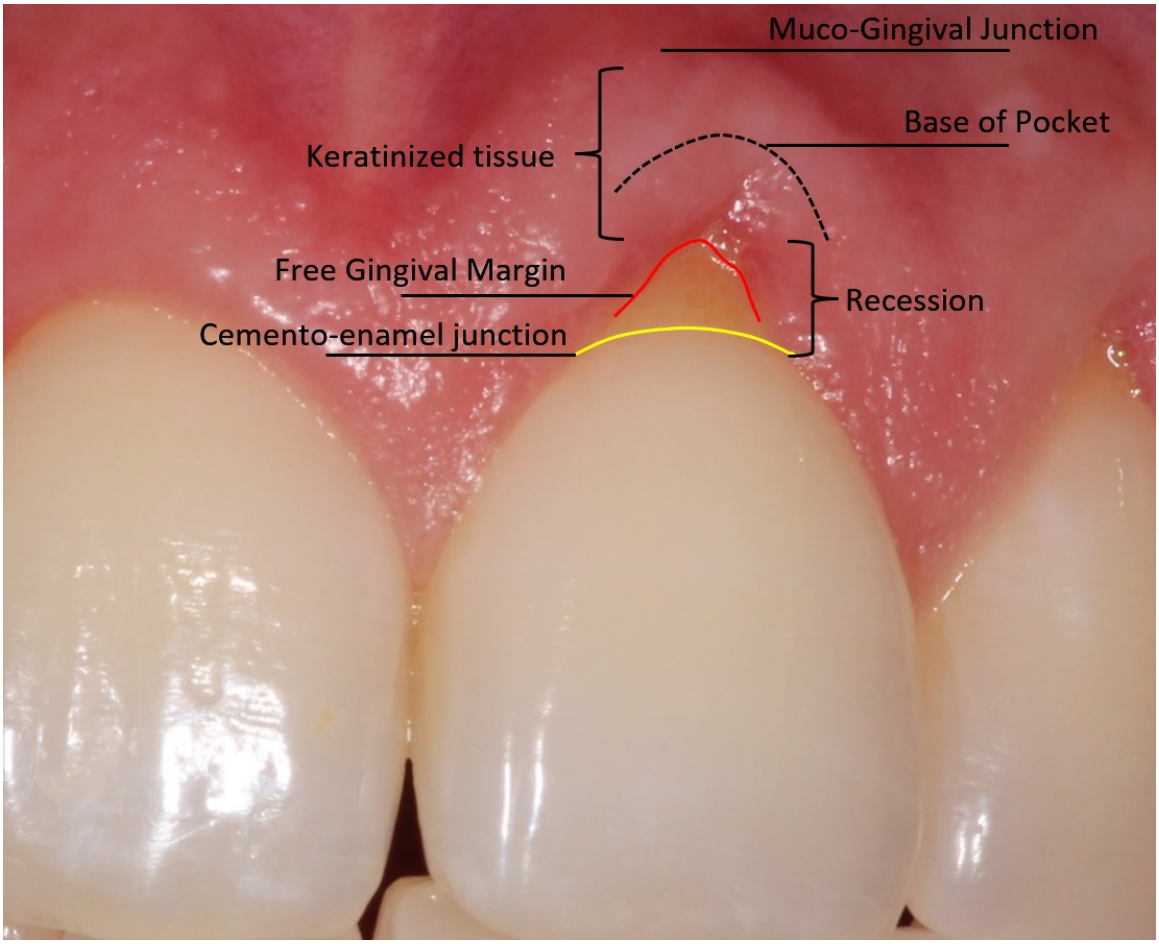
This form will be used for both Clinical and Digital data collection.

***Change in Tissue Thickness** will be recorded **only** for digital measurements. When used for Digital data collection, only GR will be recorded.

Control Tooth# _____

Experimental Tooth# _____

APPENDIX E: MEASUREMENT LANDMARKS



MEASUREMENTS

Gingival Recession (GR) = Cemento-enamel Junction to Free Gingival Margin

Probing Depth (PD) = Free Gingival Margin to Base of Pocket

Clinical Attachment Level (CAL) = Cemento-enamel Junction to Base of Pocket

Width of Keratinized Tissue (KT) = Free Gingival Margin to Mucogingival Junction

APPENDIX F: PATIENT INFORMATIONAL HANDOUT

Study on Surgical Correction of Gingival Recession
Informational Handout

The Periodontics Dept. at the Naval Postgraduate Dental School is conducting a research study evaluating the correction of gingival recession (also called gum recession) defects using tissue grafting procedures. Autografts consist of tissue taken from the roof of the mouth to serve as the grafting material to correct the defect. Autografting has been the gold standard for treating gum recession. A xenograph is graft material taken from an animal. Xenografting has gained popularity because it avoids the additional palatal surgery to harvest graft material. NPDS uses Mucograft®, a xenograft derived from pigs. It has demonstrated success similar to autographs. The collagen in Mucograft® has been tested to be free of disease and is further processed to be free of biologic contaminants. It is considered extremely safe. It employs the same surgical technique used for autografts. Emdogain, a liquid biologic material, is also derived from pigs. Emdogain used alone has also shown success in grafting procedures. Our goal is to evaluate whether adding Emdogain to Mucograft® makes a difference in the treatment of gum recession.

You have been asked to participate in this study because you have 2 teeth requiring gum recession treatment. If you decide to participate, Mucograft® will be saturated with Emdogain and used as the graft material for one tooth. Mucograft® *without* Emdogain will be used as the graft material for the other tooth. Treatment for gingival recession normally requires 7 appointments; 2 pre-operative appointments, 1 surgical date, and 4 follow-up appointments (1, 2, 4 and 6 weeks) to monitor your healing by taking measurements. A study participant will be required to return to the clinic for 2 additional appointments at 3 and 6 months following surgery to monitor healing and take measurements. If you do not wish to participate in the study, you can still to receive grafts for your gum defects at the Periodontics Clinic.

This is the first study to independently assess Mucograft® in combination with Emdogain. Both products have been approved by the Food and Drug Administration in treating gum recession defects. If you are interested in participating, a study investigator will meet with you to more thoroughly explain the study. Your participation is voluntary. Meeting an investigator does not obligate you. If you have any further questions, you can contact the principle investigator, LT Brent Tibbet at 301-319-8521. Thank you for your consideration.

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