

Evaluation of Human Recession Defects Treated with Coronally Advanced Flaps and Either Enamel Matrix Derivative or Connective Tissue. Part 1: Comparison of Clinical Parameters

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Background: Recession defects around teeth have been treated with a variety of surgical techniques. Most of the literature suggests that the subepithelial connective tissue graft has the highest percentage of mean root coverage with the least variability. Previous studies have demonstrated that enamel matrix derivative (EMD) has the ability to improve clinical parameters. The purpose of this study was to compare the clinical efficacy of enamel matrix derivative placed under a coronally advanced flap to subepithelial connective tissue placed under a coronally advanced flap in patients with recession type defects.

Methods: Twenty patients with incisors or premolars presenting with a facial recession of ≥ 4 mm in contralateral quadrants of the same jaw were treated; 17 patients completed the study. One tooth in each patient was randomized to receive either a coronally advanced flap with a subepithelial connective tissue graft (control) or a coronally advanced flap with EMD (test). Clinical parameters measured at baseline and at 6, 9, and 12 months included amount of recession; width at the coronal extent of the gingival defect; width of keratinized tissue; probing depth; clinical attachment level; inflammation score; plaque score; plaque index; alveolar bone level; tissue texture and color; and patient perception of pain, bleeding, swelling, and sensitivity.

Results: Results for both the test and control groups were similar for all measured clinical parameters with the exception of early healing, self-reported discomfort, and the amount of keratinized tissue obtained. The coronally advanced flap with EMD was superior to the subepithelial connective tissue graft with regard to early healing and patient-reported discomfort, whereas the subepithelial connective tissue graft demonstrated greater amount of keratinized tissue during the 12-month evaluation period. However, both the test and control showed a significant increase in the amount of keratinized tissue at 9 and 12 months compared to baseline. No significant difference in the amount of root coverage was found between the test and control groups ($n = 19$; $P = 0.82$). On average, a gain of 4.5 mm (range 4 to 8 mm) tissue covering the previously exposed root surfaces was achieved with both treatment groups. The average percentages of root coverage for control and test groups were 93.8% and 95.1%, respectively. One hundred percent root coverage was obtained 89.5% of the time with the coronally advanced flap with EMD and 79% of the time with the subepithelial connective tissue graft.

Conclusion: Based on the results of this investigation, the addition of EMD to the coronally advanced flap resulted in root coverage similar to the subepithelial connective tissue graft but without the morbidity and potential clinical difficulties associated with the donor site surgery. *J Periodontol* 2003;74:1110-1125.

KEY WORDS

Biometry; comparison studies; enamel matrix derivative; follow-up studies; gingival recession/surgery; gingival recession/therapy; grafts, connective tissue; periodontal regeneration; proteins, enamel matrix/therapeutic use; surgical flaps.

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Recession defects around teeth are treated to resolve a variety of patient-centered concerns including, but not limited to, root sensitivity, increased potential for root caries, difficulty in plaque control, and esthetics. A variety of surgical techniques are available to the clinician to cover denuded root surfaces.¹ A number of authors have proposed the use of the coronally advanced flap to cover denuded root surfaces as a relatively easy procedure for both the patient and the clinician.²⁻⁹ The clinical appeal of the coronally advanced flap is the simplicity of the procedure for the clinician and the reduced morbidity of the procedure for the patient because donor tissue does not need to be procured. Other papers suggest that the subepithelial connective tissue graft has not only the highest percentage of mean root coverage but also the least variability.¹⁰⁻¹² Recently, a systematic review of the literature¹³ including a meta-analysis demonstrated that the subepithelial connective tissue graft, the coronally advanced flap, and guided tissue regeneration (GTR) all produce statistically significant improvements in root coverage (60% to 84%) and clinical attachment gain. The report indicated that all three techniques achieved complete root coverage 22% to 50% of the time. The analysis also indicated that GTR membranes did not enhance the results of root coverage as compared to coronally advanced flap alone.¹³ That review reinforced the clinical experience of many clinicians by confirming that the connective tissue graft is the most predictable technique for root coverage in most situations, although the analysis did not find it to be statistically significantly better than coronally advanced flap in attaining complete root coverage.

The role of enamel matrix derivative (EMD) has been evaluated for its potential both in regeneration of intrabony defects^{14,15} and more recently in gingival recession.¹⁶⁻¹⁸ In 1997 Heijl¹⁶ demonstrated new cementum and bone gain histologically in one experimentally created recession defect. Rasperini et al.¹⁷ added EMD to a subepithelial connective tissue graft and found histological evidence of new cementum, bone, and connective tissue fibers. Modica et al.¹⁸ compared the results of coronally advanced flap with and without EMD and concluded that EMD did not significantly improve the clinical outcome of gingival recession treated by coronally advanced flap, even though the test group demonstrated slightly better results in root coverage.

Based on this information, it would seem reasonable to compare the coronally advanced flap plus EMD to the subepithelial connective tissue graft. Therefore, the aim of this randomized, controlled, single-center, split-mouth design study was to compare the clinical efficacy of EMD placed under a coronally advanced flap (test group) to subepithelial connective tissue placed under a coronally advanced flap (control group) in patients with recession type defects. All patients were

followed for 12 months, and one patient donated two hopeless teeth, which permitted histologic comparison of the two procedures. The histologic analysis is presented in a separate paper as part 2 of this report.¹⁹

MATERIALS AND METHODS

Study Population

Twenty patients with Miller's Class II²⁰ buccal gingival recession of ≥ 4 mm and width ≥ 3 mm on teeth in contralateral quadrants of the same jaw who met the inclusion/exclusion criteria were selected from patients seeking treatment in the author's private practice. The patient population, ranging in age from 23 to 62 (mean age 44.9 years, SD:11.6), included 10 men and 10 women. A written Institutional Review Board-approved consent form regarding the study was obtained from each patient. All patients agreed to participate in the study and gave their informed consent. Of the 20 patients, 18 (90%) were of Caucasian descent, 1 was Hispanic (5%), and 1 (5%) Asian. Fifteen patients (75%) were non-smokers and 5 patients (25%) were former smokers (mean years since smoking cessation 18.6, SD: 6.8). All teeth had ≤ 2.5 mm of keratinized tissue at baseline and a minimum of 4 mm of recession. One patient had mandibular teeth treated, all other defects were in the maxillary arch. Occlusal interferences were identified and eliminated through occlusal adjustment, and hard acrylic biteguards were constructed for those patients with parafunctional habits. Because of the study design, each patient served as his or her own control, so that extraneous factors such as oral hygiene, compliance, etc. would be controlled within each subject.

Clinical Evaluation

At baseline and postsurgical follow-ups, the treated sites were clinically examined, defect measurements recorded, and clinical photographs taken. Radiographs were taken at baseline and 12 months. The primary efficacy parameter was recession depth. The secondary efficacy parameters included clinical attachment level, probing depth reduction, and gingival height.

Baseline parameters included: depth of the gingival defect, width at the coronal extent of the gingival defect, width of keratinized tissue (mucogingival junction), probing depth at the point of the gingival defect, clinical attachment level at the point of the gingival defect, proximal probing depths, proximal clinical attachment levels, root dentin hypersensitivity, inflammation score, plaque score of each tooth selected for gingival grafting, overall plaque index, alveolar bone level, and position of the gingival margin. A judgment of healing at 1 week was made on a visual analog scale with "much worse than expected" on one end, "much better than expected" on the other end, and "expected" in the center. The examiner checked for the presence

of root dentin hypersensitivity using a conventional air blast for 3 seconds after isolating the neighboring teeth. The root dentin hypersensitivity was registered as none, moderate, or severe. The inflammation score was recorded according to the criteria of the modified gingival index presented by Lamster et al.²¹ Plaque score of the test and control teeth was recorded as presence or absence of plaque at the gingival margin and overall plaque index was evaluated using the modified O'Leary plaque index. Tissue texture was assessed by comparing test and control grafts to surrounding tissues and scoring it as more, less, or equally firm. Similarly color of test and control grafts were compared to surrounding tissue and scored as more, less, or equally red. Patient perception of pain, bleeding, swelling, and sensitivity was evaluated by questionnaire. Alveolar bone level was recorded as the distance between the cemento-enamel junction (CEJ) and the buccal alveolar bone crest, measured to the nearest 0.5 mm. The gingival margin was recorded as the distance between the CEJ and the buccal soft tissue margin measured to the nearest 0.5 mm. Data were collected over time for plaque scores; tissue texture; tissue color; and for patient perception of pain, bleeding, swelling, and sensitivity. Baseline measurements were repeated at 3, 6, 9, and 12 months. All preoperative and postoperative clinical assessments were made by a single blinded examiner, not the operator. Training and calibration was conducted prior to the start of the study to ensure intra-examiner reproducibility with respect to measurement of the outcome variables. At the time of surgery, the operator recorded at the alveolar bone level, the immediate postsurgical position of the gingival margin of the test and control graft, and probing depths, using an automated probe with a constant force of 25 grams and a 1 mm graded tip.

Surgical Procedure

Following the screening examination, all subjects received oral hygiene instructions, and patients were not appointed for surgery until they achieved a modified O'Leary plaque index score of less than 85%.

The test and control treatments were performed at the same surgical appointment. The first surgery was always performed on the left side with the recession defect treated either with the test or control procedure according to a computer generated randomization list. Immediately prior to surgery, the surgeon opened an envelope labeled with the patient's number which contained the treatment assignment.

Surgical protocol for test treatment with coronally advanced flap plus EMD. Following local anesthetic, the exposed root surface was planed and scaled using (as needed) chisels, curets, and finishing burs to remove plaque, accretions, and root surface irregularities and to reduce root prominence. A sulcular incision was

made at the site of recession, and the incision was extended horizontally into the adjacent interdental areas slightly coronal to the tooth's CEJ. The horizontal incisions were connected to vertical releasing incisions both mesially and distally. A full thickness flap was elevated in an apical direction until the mucogingival junction (MGJ) had been passed. The periosteum was then cut and a blunt dissection into the vestibular lining mucosa was made to eliminate tension so that the flap could easily be positioned coronally at the level of the CEJ. The facial portion of the interdental papilla was de-epithelialized to create a connective tissue bed for suturing the coronally advanced flap.

The exposed root surface was conditioned with 24% EDTA[‡] for 2 minutes following the manufacturer's instructions and thoroughly rinsed with saline. The root surface was dried and EMD[§] was applied. The root surface was then covered with the coronally advanced flap and secured with 5-0 gut sutures into the de-epithelialized papilla at the level of the CEJ. Both vertical incisions were closed with sutures. No pressure was applied to the flap after suturing.

Surgical protocol for control treatment with coronally advanced flap and connective tissue. This surgical procedure was identical to the one used for the test treatment with the exception that the mucosal flap was partial thickness, not full thickness. The root surface was conditioned with 24% EDTA, and a subepithelial connective graft was placed over the denuded root surface. The donor area for the subepithelial connective tissue was the palate in the bicuspid region on the same side as the control graft. Donor palatal tissue was harvested in the following way: a horizontal incision was placed in the palate 2 to 3 mm from the free gingival margin, and two parallel internal vertical incisions, one superficial and one deep, were made and connected mesially and distally. The underlying connective tissue was released at its base and removed. The graft was shaped to fit the recipient site and sutured to the papilla on either side of the graft. The graft was also sutured to the adjacent attached gingiva coronal to the mucogingival junction on either side of the denuded root. In addition, a suspensory suture was placed in the periosteum apical to the graft and looped around the neck of the tooth to provide a secure adaptation of the graft to the root surface. The flap was then coronally advanced over the graft as previously described for the test site. Pressure was applied to the graft after suturing.

All subjects received instruction in proper oral hygiene measures. Patients were instructed not to brush the teeth in the treated areas but to use 0.12% chlorhexidene gluconate mouthrinse^{||} for 1 minute twice

‡ PrefGel, Biora AB, Malmo, Sweden.

§ Emdogain, Biora AB.

|| Peridex, Procter & Gamble, Cincinnati, OH.

daily for the first 3 weeks. Patients were instructed to avoid excessive muscle traction or trauma to the treated areas for the first 3 weeks. After this period, patients were instructed in a brushing technique that minimized apically directed trauma to the soft tissue of the treated teeth. After 4 weeks, the patients were instructed in normal tooth brushing, and all patients were recalled for prophylaxis treatment after months 1, 3, 6, 9, and 12. All patients were seen 1 week post-surgery and at months 1, 2, 3, 6, 9, and 12. At these visits, any adverse events were recorded, recession measurements made, clinical photographs obtained, and oral hygiene instructions reviewed. At months 6, 9, and 12 all clinical measurements were recorded along with the information mentioned above.

Statistical Methods

An intent-to-treat analysis was conducted throughout so that all available data were included at each time point. Summary statistics were computed for baseline measures as well as follow-up measures. Statistical analyses of probing depth, clinical attachment level, and plaque scores for surgical sites were conducted using repeated measures of analysis of covariance (ANCOVA) with baseline measures included as a covariate and subject included in the model to account for the split-mouth design. Pairwise analyses of all outcome variables were also conducted for each follow-up time point.

Baseline clinical measurements are shown in Table 1. Wilcoxon signed rank tests were conducted to compare the baseline parameters of test and control sites, and no statistically significant differences were found.

The primary efficacy variable was the absolute change in recession depth. Secondary efficacy variables were the absolute change in clinical attachment level, absolute change in probing depth, and amount of keratinized tissue. The primary and secondary variables were analyzed using ANCOVA. This model allowed for variation due to patient, site (left/right), treatment, and sequence of treatments. Also the baseline value was included in the model to increase precision.

Sample size determination. Calculations at 5% significance level show that 20 patients were sufficient to detect a difference of 1.0 mm in change in recession depth, with 95% power and assuming a within patient variation (standard deviation, estimated from previous studies with similar inclusion/exclusion criteria) of 1.0 mm. Of the 20 patients enrolled, three patients did not complete the study. One patient moved out of the country, one had a change in job and could not comply with study schedule, and the other patient was not compliant and was exited from the study. Although three subjects were lost to follow-up, complete data

Table 1.
Summary Statistics of Baseline Clinical Parameters

Parameter	Mean	SD	Median	Min	Max
Plaque score					
Control	0.70	0.801	0.5	0.0	2.0
Test	0.60	0.681	0.5	0.0	2.0
Inflammation score					
Control	1.10	0.788	1.0	0.0	3.0
Test	0.95	0.759	1.0	0.0	2.0
Recession depth					
Control	4.25	0.716	4.0	3.0	6.0
Test	4.25	0.444	4.0	4.0	5.0
Recession width					
Control	6.40	1.57	6.5	3.0	9.0
Test	6.10	1.68	6.0	3.0	10.0
Probing depth					
Control	1.80	0.834	2.0	1.0	4.0
Test	1.80	0.834	2.0	1.0	4.0
Mesial probing depth					
Control	2.50	0.607	2.0	2.0	4.0
Test	2.80	0.768	3.0	2.0	5.0
Distal probing depth					
Control	2.40	0.503	2.0	2.0	3.0
Test	2.40	0.598	2.0	2.0	4.0
Clinical attachment level					
Control	6.10	0.912	6.0	5.0	8.0
Test	6.15	1.226	6.0	5.0	9.0
Mesial CAL					
Control	0.20	0.523	0.0	0.0	2.0
Test	0.10	0.308	0.0	0.0	1.0
Distal CAL					
Control	0.15	0.366	0.0	0.0	1.0
Test	0.10	0.308	0.0	0.0	1.0
Mucogingival junction					
Control	2.50	0.889	2.0	1.0	4.0
Test	2.40	0.771	2.0	1.0	4.0
Alveolar bone level					
Control	6.13	1.43	6.0	1.0	9.0
Test	6.50	1.57	6.0	5.0	12.0
Overall plaque index	21.0	10.1	20	10	50

for all 20 subjects were available for the first 3 months of follow-up, and complete data for 19 were available for 6 months of follow-up. The only time that data were missing for all three subjects that failed to complete the study was at the 12-month follow-up. Based on percent root coverage for all 20 subjects after 3 months, we had the power to detect a 10% difference in root coverage with over 80% power after 3 months. For the 19 subjects included in analysis of 6-month follow-up, we had 70% power to detect a 10% difference in root coverage after 6 months.

RESULTS

For all clinical parameters evaluated post-treatment and over time, the results were similar between the test and control groups, with the exception of early healing, early patient-reported discomfort, and the width of keratinized gingiva. Repeated measures of analysis of variance revealed no significant differences between test and control sites over time for plaque scores, root dentin hypersensitivity, inflammation score, swelling, tissue color, and tissue texture. Similarly, Wilcoxon signed rank tests at each time point demonstrated no statistically significant differences between test and control sites at any time point for any of these parameters. Clinical attachment level from baseline to 12 months demonstrated no statistically significant difference in the change in clinical attachment level between test and control groups ($P = 0.753$) (Fig. 1).

Healing was evaluated 1 week following surgery based on a visual analog scale as “much worse than expected,” “expected,” and “much better than expected.” There was no difference in healing between the test and control sites in half of the subjects. At 1 week, in nine (45%) subjects, the healing at the test site was superior to the healing at the control site, while only one (5%) subject experienced superior healing at the control site compared to the test site. Healing at 1 week was tested using a chi-squared test of

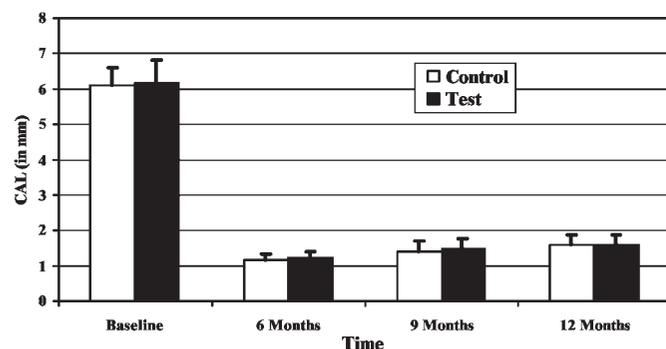


Figure 1.
Changes in clinical attachment level over time by treatment group.

independence. Test sites were found to be significantly superior in healing after 1 week compared to control sites ($P = 0.011$). This difference in early healing can also be observed clinically as seen in Figure 2.

Table 2 shows the adjusted mean clinical parameters over time with 95% confidence intervals as obtained from repeated measures of analysis of covariance with the baseline clinical parameter for each model included as a covariate. The only significant differences between test and control groups over the time periods were for probing depth with test sites having significantly smaller probing depths ($P = 0.030$) and for the MGJ margin with the test sites also exhibiting smaller values for MGJ margin ($P < 0.001$).

The primary efficacy parameter was the change in depth of the recession defect. On average, a gain of 4.5 mm (range 4 to 8 mm) of tissue covering the previously exposed root surfaces was achieved with both treatment groups. Repeated measures for analysis of covariance, while controlling for subject were performed. There was no statistically significant difference in recession depth between the test and control groups at 12 months ($P = 0.168$). However, test sites had significantly less recession than control sites at 4 weeks ($P = 0.026$), and test sites had significantly less recession than control sites at 8 weeks ($P = 0.049$). In addition, the trend in Figure 3 shows that test sites tended to have less recession over time than control sites, although this trend was not statistically significant.

Percentage of root coverage obtained for control and test sites was evaluated. Analysis of covariance with adjustment for differences in baseline depth and baseline width, while controlling for subject, was conducted. No significant difference in the percentage of root coverage was found between the test group and the control group ($P = 0.82$). At the end of 12 months, 93.8% of the root surfaces treated with coronally advanced flap plus subepithelial connective tissue graft were covered, whereas 95.1% of the root surfaces treated with coronally advanced flap plus EMD were covered. One hundred percent root coverage was obtained 89.5% of the time with the coronally advanced flap with EMD and 79% of the time with the subepithelial connective tissue graft.

The secondary efficacy parameters included probing depth reduction and width of keratinized gingiva. Figure 4 refers to adjusted mean changes in probing pocket depth over time with 95% confidence intervals as obtained from repeated measures of analysis of covariance with the baseline clinical parameter by treatment group. Minimal changes were evident at all time intervals in either the test or control groups. Other than at 6 months, there were no significant differences in probing depth measurements between the two groups.

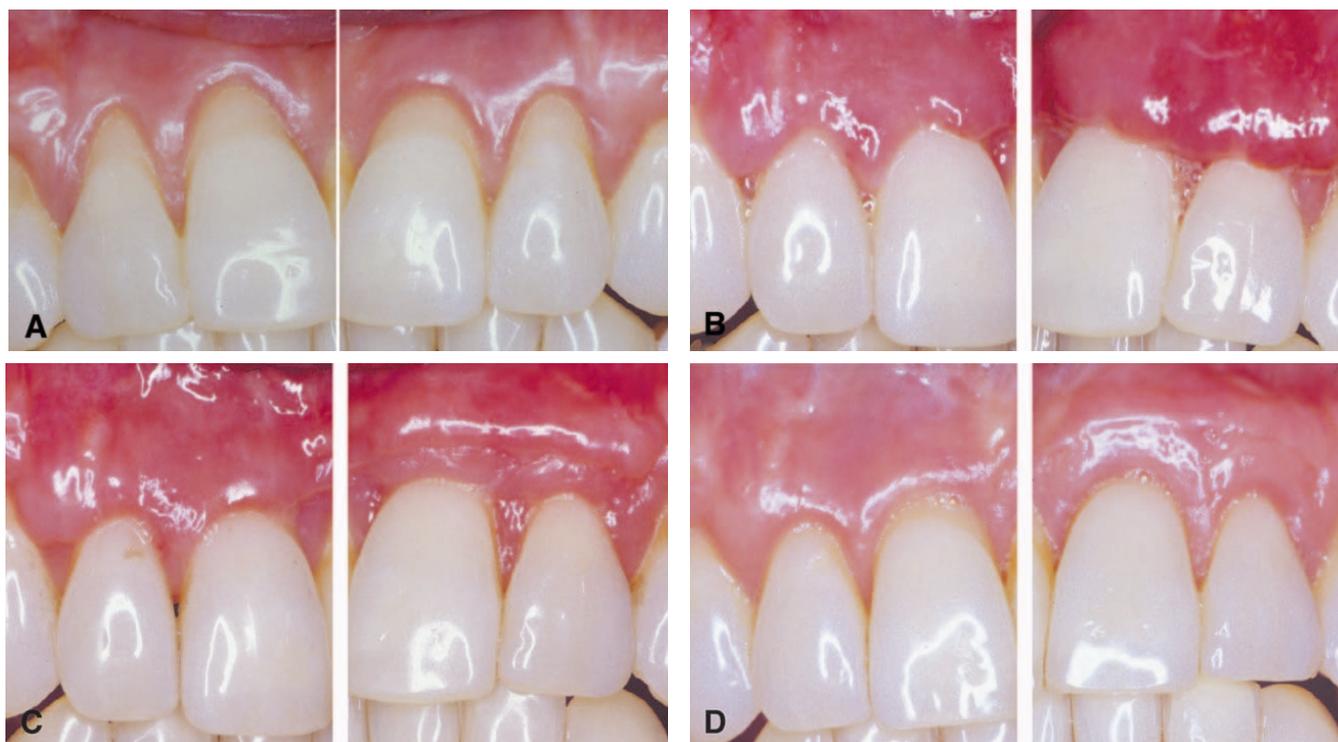


Figure 2.

A) Baseline appearance of the maxillary lateral incisors which were randomized to receive the test (left) or control (right) treatment. **B)** At 1 week following treatment, the test (left) treatment exhibits fewer clinical signs of inflammation as compared to the control (right) tooth. **C)** Test (left) and control (right) teeth at 4 weeks, the test treatment continues to exhibit superior wound healing. **D)** At 12 months postsurgery, the recreation of a functional and esthetic morphology of the mucogingival complex is clinically demonstrated.

Figure 5 shows the change in the amount of keratinized tissue over time up to 12 months between test and control groups. Again, repeated measures of analysis of covariance were utilized to evaluate the level of the MGJ margin over time with adjustment for subject and baseline MGJ margin. At baseline, all sites exhibited ≤ 2.5 mm of keratinized tissue. Following treatment, there was a statistically significant difference in the amount of keratinized tissue between the control and test groups at 6, 9, and 12 months. An overall significant difference in the level of the MGJ for the 12 months between test and control sites was found ($P = 0.0005$). Wilcoxon signed rank tests were also conducted to verify these results and, again, significant differences were found between test and control sites. There was consistently more keratinized tissue evident with the subepithelial connective tissue graft (control) than the coronally advanced flap with EMD (test). Furthermore, there was a statistically significant difference in the amount of keratinized tissue evident within the control group between baseline and all examined time intervals: 6 months: $P = 0.0001$; 9 months: $P = <0.0001$; and 12 months: $P = <0.0001$. The P values for Wilcoxon signed rank tests comparing each time point to baseline

for the test group demonstrated statistically significant differences in the amount of keratinized tissue relative to baseline and 9 months ($P = 0.0078$) and 12 months ($P = 0.0156$) postoperative, but not at 6 months ($P = 0.2451$). In both groups, there was a trend toward increasing amounts of keratinized tissue over time.

Figure 6 depicts the results of the patient questionnaire regarding discomfort levels over time between the two treatment groups. Chi-squared tests of independence were conducted at each time point to determine if there was an association between treatment group and level of discomfort. At 1 month, nine patients (45%) reported high discomfort levels associated with the control treatment as opposed to one patient (5%) within the test group. This difference was statistically significant ($P = 0.011$). Ten patients (50%) reported no differences in discomfort between the two treatments. At 3 months, five patients (25%) reported discomfort with the control treatment as opposed to three patients (15%) reporting discomfort with the test treatment. After 6 months, differences in discomfort levels between the two groups were minimal.

Clinical observation of the results obtained with both procedures reinforced the equivalency of these procedures and demonstrated therapeutic outcomes in accor-

Table 2.
Clinical Parameters at Various Times (95% confidence levels in parentheses)

	3 Months	6 Months	9 Months	12 Months	P*
Plaque score					
Control	0.59 (0.29 to 0.89)	0.12 (-0.10 to 0.34)	0.12 (-0.06 to 0.29)	0.06 (-0.16 to 0.28)	0.722
Test	0.35 (0.05 to 0.66)	0.24 (0.02 to 0.45)	0.24 (0.06 to 0.41)	0.18 (-0.04 to 0.39)	
Recession					
Control	0.29 (0.03 to 0.56)	0.29 (0.05 to 0.54)	0.35 (0.08 to 0.63)	0.24 (-0.04 to 0.51)	0.281
Test	0.12 (-0.15 to 0.38)	0.06 (-0.18 to 0.30)	0.12 (-0.16 to 0.39)	0.18 (-0.10 to 0.45)	
Probing depth					
Control	—	1.47 (1.30 to 1.64)	1.65 (1.43 to 1.86)	1.71 (1.43 to 1.99)	0.030
Test		1.18 (1.01 to 1.35)	1.35 (1.14 to 1.57)	1.41 (1.13 to 1.69)	
Clinical attachment					
Control	—	1.18 (1.02 to 1.34)	1.41 (1.14 to 1.69)	1.59 (1.30 to 1.88)	0.753
Test		1.24 (1.07 to 1.40)	1.47 (1.20 to 1.74)	1.59 (1.30 to 1.88)	
Mucogingival junction					
Control	—	3.71 (3.37 to 4.05)	3.94 (3.61 to 4.27)	4.06 (3.76 to 4.37)	<0.001
Test		2.76 (2.42 to 3.10)	3.12 (2.79 to 3.45)	3.11 (2.80 to 3.42)	

* P values are for overall group comparisons from repeated measures ANCOVA with only the time periods listed included and baseline measurements corresponding to each outcome included as a covariate.

dance with the treatment objectives. Figure 2D shows a direct comparison of the clinical outcomes at 1 year. Figures 2A and 2D depict the before and after treatment and clearly demonstrate the recreation of a functional and esthetic morphology of the mucogingival complex.

At the conclusion of the study, only one patient exhibited any ongoing adverse reaction. In this individual, the control site was still exhibiting mild pain, and the test site was still exhibiting mild sensitivity. The only reported adverse events included pain,

swelling, bleeding, bruising, and sensitivity and these events were similarly distributed among test and control sites. Control sites yielded more severe adverse observations including self-reported patient discomfort, the amount of root surface sensitivity present, postoperative swelling, and bleeding.

DISCUSSION

The purpose of this randomized, controlled, single-center, split-mouth design study was to compare the

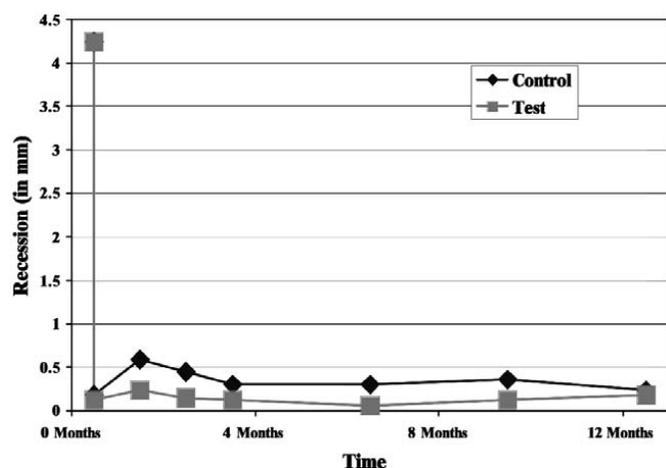


Figure 3.
Root coverage over time by treatment group.

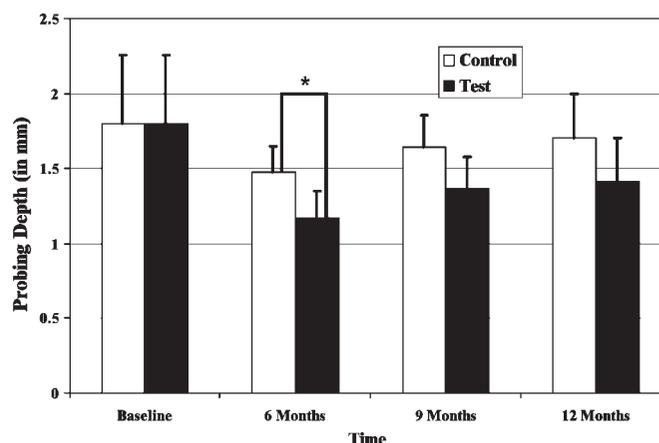


Figure 4.
Adjusted mean change in probing depth over time by treatment group.
*Statistically significant.

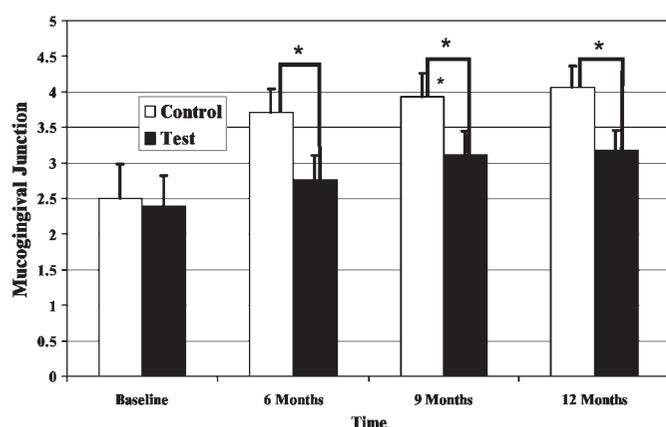


Figure 5.
Change in the amount of keratinized tissue over time by treatment group.
*Statistically significant.

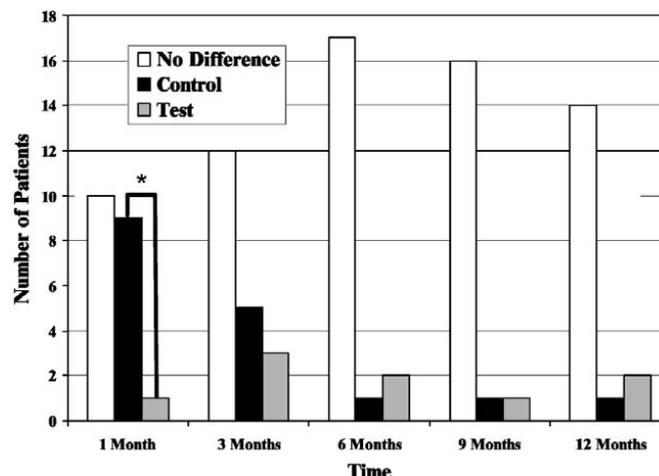


Figure 6.
Discomfort levels over time by treatment groups. *Statistically significant.

clinical efficacy of EMD placed under a coronally advanced flap (test) to a subepithelial connective tissue graft placed under a coronally advanced flap (control) in patients with recession type defects. The summary of the evidence indicates that both procedures are highly effective in covering recession defects with the coronally advanced flap with EMD representing a simpler procedure for the clinician and a less invasive procedure for the patient.

Trombelli²² suggested that the goal of root coverage procedures should include regeneration of the lost attachment apparatus including the formation of new cementum with inserting connective tissue fibers, alveolar bone regeneration, and recreation of a functional and esthetic morphology of the mucogingival complex. This paper has demonstrated that test and control treatments both

fulfill the requirement of the recreation of a functional and esthetic morphology of the mucogingival complex over previously denuded root surfaces (Figs. 7 and 8). The second paper in this series¹⁹ addresses the requirement of regeneration of the lost attachment apparatus.

According to a 1996 literature review,¹ the subepithelial connective tissue graft demonstrated the highest success rates, averaging almost 4 mm of attachment level gain and covering, on average, 91% of the exposed root. As mentioned earlier, the predictability of the subepithelial connective tissue graft was reconfirmed by a systematic review presented at the 4th European Academy of Periodontology Workshop.¹³ As such the use of the subepithelial connective tissue graft is clearly the preferred treatment of choice in most mucogingival recession defects.

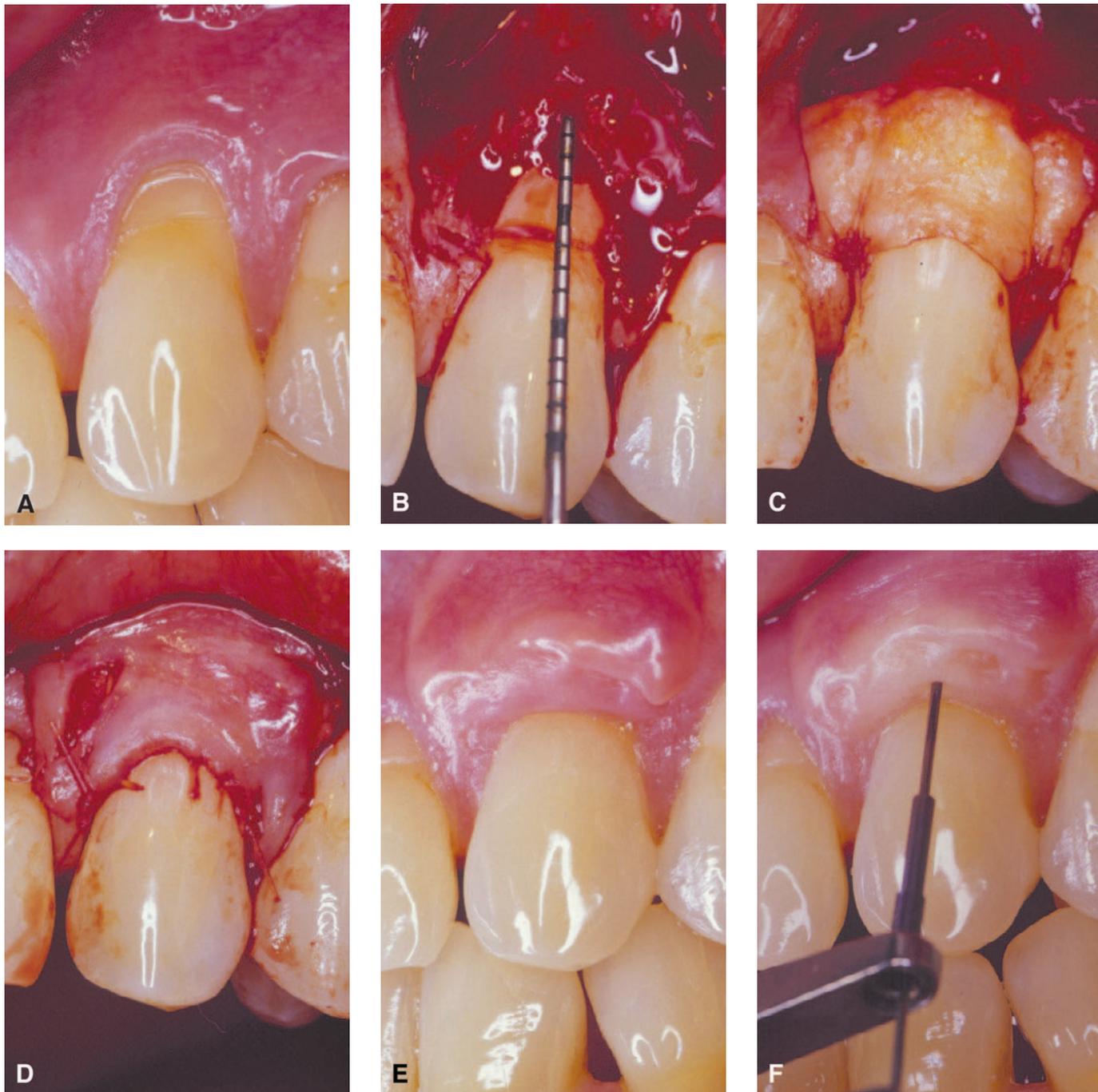


Figure 7.
A) Preoperative photograph of a maxillary cuspid in patient #20 randomized to receive a subepithelial connective tissue graft (control).
B) Intraoperative measurements are made. **C)** Subepithelial connective tissue graft is sutured over the denuded root surface. **D)** The mucogingival flap is coronally advanced over the subepithelial connective tissue graft and sutured. **E)** Clinical appearance of the control tooth at 12 months. **F)** Probing depth measurements on control tooth at 12 months. Note absence of clinical signs of inflammation.

Many studies have evaluated the addition of various materials placed under the coronally advanced flap in an effort to improve root coverage and to eliminate the need for a secondary surgical site to harvest the connective tissue. Recently, Tatakis and Trombelli²³ com-

pared connective tissue grafting and GTR techniques using a polyglycolic acid barrier. They reported no significant differences in percentage of root coverage or prevalence of 100% root coverage between the two groups with 96% root coverage and 83% complete root

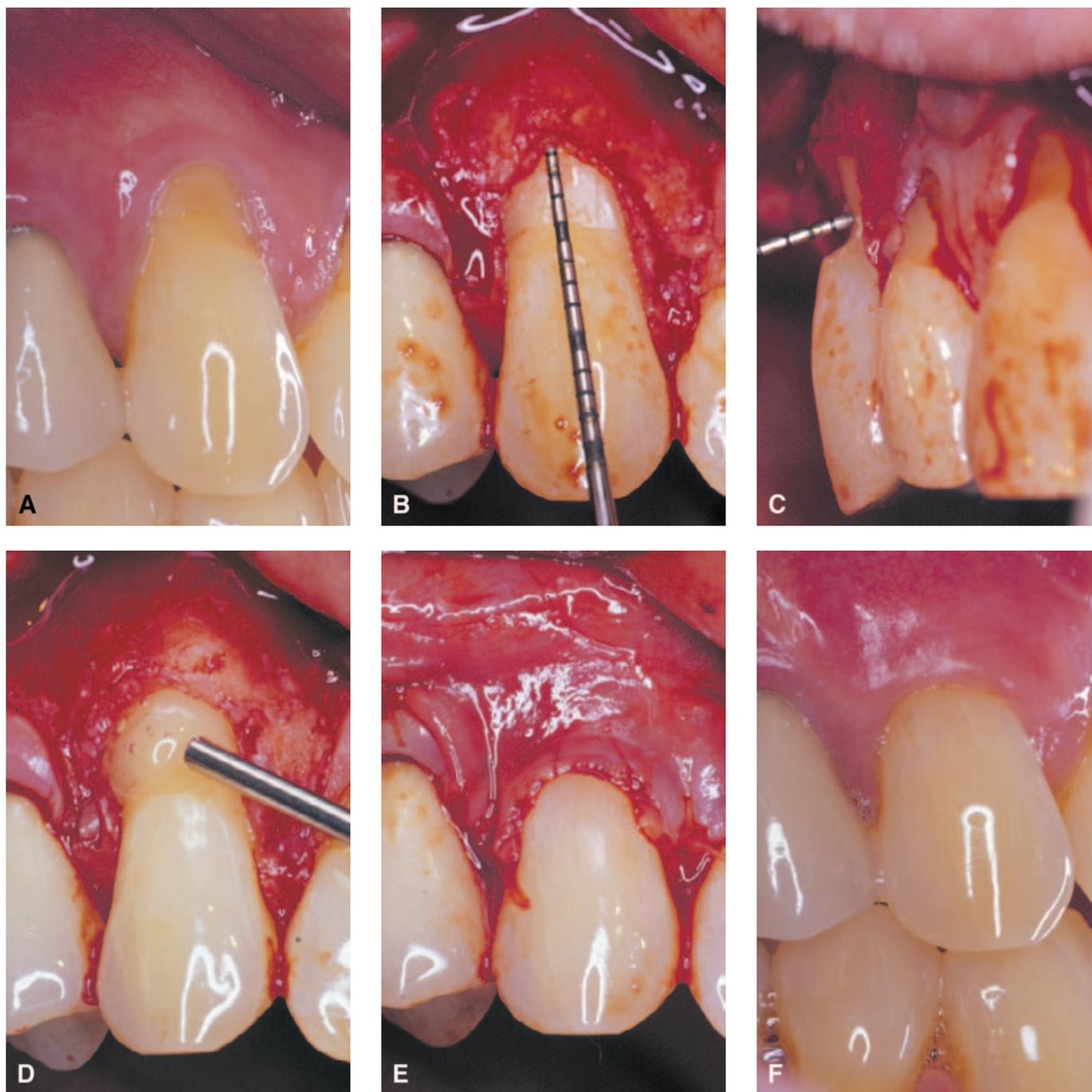


Figure 8.

A) Preoperative photograph of a maxillary cuspid in patient #20 randomized to receive the coronally advanced flap with EMD (test). **B)** Intraoperative measurements are made. **C)** Note the amount of axial abrasion present. **D)** The EMD is applied to the root surface. **E)** The mucogingival flap is coronally advanced over the root surface and sutured. **F)** Clinical appearance of the test tooth at 12 months.

coverage for the connective tissue group and 81% root coverage and 58% complete coverage for the GTR group. Even though it was not significant, the percentage of root coverage and the prevalence of complete root coverage clearly favored the subepithelial connective tissue graft. Aichelman-Reidy et al.²⁴ com-

pared acellular allogenic dermal connective tissue and autogenous palatal connective tissue under coronally advanced flaps for the treatment of gingival recession. They reported actual root coverage of 65.9% (average baseline recession depth of 2.5 ± 0.8 mm) with allogenic dermal connective tissue and 74.1% (average

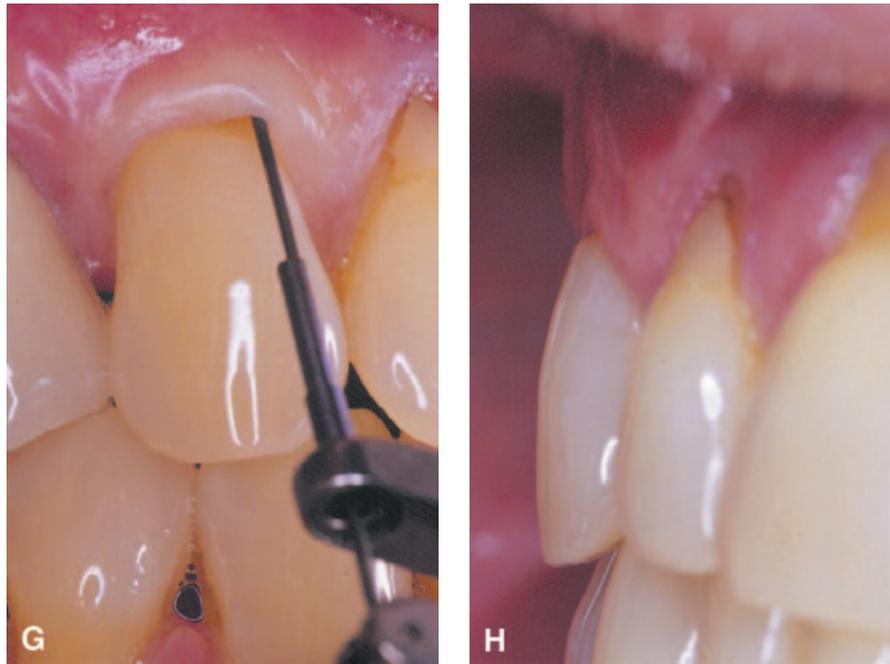


Figure 8. (cont.)

G) Probing depth measurements on the test tooth at 12 months. Note the absence of clinical signs of inflammation. **H)** A profile photograph of the test tooth at 12 months demonstrating the creation of a proper soft tissue to tooth emergence profile despite the significant root surface abrasion.

baseline recession depth of 3.0 ± 0.7 mm) with palatal connective tissue. Wang et al.²⁵ compared the use of a collagen membrane to connective tissue. The collagen membrane treated sites produced mean root coverage of $73\% \pm 26\%$ (average baseline recession depth 3.7 ± 1.1 mm) and connective tissue produced mean root coverage of $84\% \pm 25\%$ (average baseline recession depth 3.4 ± 1.0 mm). Both of the above-mentioned studies demonstrated a great deal more variability than did this study with mean root coverage of $93.8\% \pm 7.9\%$ (average baseline recession depth 4.25 ± 0.72 mm) for the control group and a mean root coverage of $95.1\% \pm 7.9\%$ (average baseline recession depth 4.25 ± 0.44 mm) for the test group in the current study.

Only a few clinical investigations have been reported in the literature supporting the use of EMD in treatment of recession defects. Most of the scientific and clinical research to this point has emphasized the safety of EMD and the efficacy of this material in the treatment of periodontal intrabony defects. To date, the clinical publications, usually case reports, on the use of EMD in the treatment of human recession defects have reported favorable results for this treatment alternative. In 1997, Hammarström et al.²⁶ published on the effectiveness of EMD in the periodontal regeneration of fenestration defects using the monkey animal model. The buccal plate along with the exposed periodontal

ligament and cementum were removed on the maxillary canine to first molar. Various preparations of EMD with and without delivery vehicles were applied, and the flaps were repositioned and allowed to heal for 8 weeks. Healing was evaluated with light microscopy and morphometric comparison of the various combinations made. Only the polyglycolic acid vehicle with EMD resulted in significant regeneration of the periodontal apparatus. In 2000, Sculean and coworkers²⁷ published a comparison of GTR and EMD in a monkey model. In 1998, Biancu²⁸ published a case report on a 23-year old non-smoking patient treated for two recession defects using EMD with coronally advanced flaps. After 6 months, he reported a 3 to 4 mm gain in attachment. In that same year, Siervo and Corani²⁹ reported a 1.5 mm gain from their 12-month postsurgical evaluation using EMD in treating four mucogingival recession defects (Miller Class I) in two patients.

Modica and coworkers¹⁸ reported on the efficacy of the coronally advanced flap with and without the use of EMD using a split-mouth study design. Fourteen pairs of comparable defects were included in this study from 12 patients. Gingival recession, clinical attachment levels, probing depth, and amount of keratinized tissue were recorded at baseline and again at 6 months. The average root coverage reported for the test group (with EMD) was 3.36 mm or 91.2%. Complete root coverage was achieved in 64% of test sites and 50% of the controls. It is also interesting to note that the corresponding data for the coronally advanced flap alone was 2.71 mm or 80.9%. Likewise, these results are comparable to those of Wennström,¹ who reported that the calculated average percentage of root coverage for coronally advanced flap studies was 83% with an average gain in clinical attachment of about 3 mm. Equally noteworthy in the Italian study¹⁸ is that, even though the test group showed better results for the amount of root coverage and clinical attachment levels, the difference was not significant. No changes were reported for probing depth and the amount of keratinized tissue. Jepsen et al.³⁰ reported on using coronally advanced flap with EMD to cover multiple gingival recession defects. At 12 months, the procedure achieved 82% (SD: 17%) recession coverage (mean baseline recession depth, 4.2 mm; SD, 1.2 mm) and

the mean probing depth at 12 months was 2 mm. The results of both of these studies, although not as strong, nicely complement the findings of the current study.

This study demonstrated that there was no statistically significant difference in probing depths at baseline and between the two procedures at all time intervals. Both procedures resulted in a probing depth of less than 2 mm, which was maintained for at least 12 months. The type of attachment to the root surface gained through these two procedures will be addressed in the second paper in this series,¹⁹ but it is obvious not only from the statistical results (Fig. 4), but also from the clinical results depicted in Figures 7F and 8G that the grafts resulted in root coverage with no visible signs of inflammation and minimal probing depths even when recorded under 25g of pressure.

Most patients are not interested in what percent of the root surface they can expect a particular technique to cover. They want to know how often they can expect complete root coverage. The present study obtained 100% root coverage 89.5% of the time with coronally advanced flap plus EMD (test) and 79.0% of the time with the subepithelial connective tissue graft (control). Mean root coverage with the test treatment was 95.1% and 93.8% with the control. In comparison, Miller³¹ using a thick free autogenous graft, obtained 100% root coverage in 90% of Class I and II defects with a mean root coverage of 92.7%. Using a similar type graft, Holbrook and Ochsenbein³² reported 100% root coverage 44% of the time; Nelson³³ reported 100% root coverage in 62% of his subpedicle connective tissue graft cases and a mean root coverage of 91%. Raetzke¹⁰ covered the root surface 100% of the time in 41.7% of his cases through the use of the connective tissue envelope graft and reported a mean root coverage of 80%. Pini Prato et al.³⁴ obtained a mean root coverage of 72.7% using GTR to cover denuded root surfaces. Other reports using GTR demonstrated similar mean root coverage results: Trombelli et al.³⁵ 77%, Tinti et al.³⁶ 77%, Tinti and Vicenzi³⁷ 74%, and Waterman³⁸ 76%. Harris³⁹ recently evaluated the long-term stability of root coverage following GTR and found that the amount of root coverage gained was not stable over time.

The present investigation has shown statistically equivalent results between these two treatment modalities with regard to the following clinical parameters as compared to baseline and over time up to 12 months: clinical attachment levels, root coverage, probing depths, plaque scores, root dentin sensitivity, inflammation, swelling, average tissue color, and tissue textures. Based on percent root coverage, the current study has 80% power to detect a difference of 11.2% in root coverage. In addition, this study has

95% power to detect a difference of 0.5 mm in recession depth between groups. Hence, the current study had adequate power to detect a statistically significant difference in root coverage, if such a difference existed. The only significant differences observed between these two procedures related to early healing, patient reported discomfort, and the amount of keratinized tissue.

One of the well-recognized benefits with the subepithelial connective tissue graft is the amount of keratinized tissue consistently produced. Wennström and Zucchelli⁵ reported no statistically significant differences between coronally advanced flaps alone and in combination with a subepithelial connective tissue graft, with the exception of the increase in gingival height where the combination therapy resulted in over twice the gingival height, 2.8 mm as opposed to 1.1 mm. In their investigation of subepithelial connective tissue grafts with and without citric acid root conditioning for the treatment of recession defects, Bouchard et al.⁴⁰ reported similar findings, although the differences were not statistically significant. Wang et al.²⁴ reported 0.7 mm gain in keratinized tissue with coronally advanced flap over a collagen membrane as compared to 1.1 mm gain in keratinized tissue with the subepithelial connective tissue graft. Hägewald et al.⁴¹ reported a significant gain in keratinized tissue with coronally advanced flap plus EMD. The present investigation again reinforces these findings, but with fewer differences. At 12 months, the average gain in keratinized tissue was 4.06 mm for the subepithelial connective tissue graft (control) versus 3.11 mm for the coronally advanced flap with EMD (test). Even so, these results represent significant differences between the test and control at 12 months and all other evaluated time periods. Consistently, there was more keratinized tissue measured with the control group than with the test group. Furthermore, the amount of keratinized tissue within the control group was significant from baseline over all measured time periods (6, 9, and 12 months). The interesting observation in both the test and control groups was even though the test group exhibited significantly less keratinized tissue than the control, the amount of keratinized tissue measured increased over time with a significant difference in the amount of keratinized tissue evident at 9 and 12 months compared to baseline. In both groups, there was a trend toward increasing amounts of keratinized tissue over time as demonstrated statistically in Figure 5 and clinically in Figures 9 and 10. Cordioli et al.⁴² reported that when connective tissue is combined with a coronally advanced flap to treat recession defects, the palatal subepithelial connective tissue grafted beneath the alveolar mucosa did not seem to induce

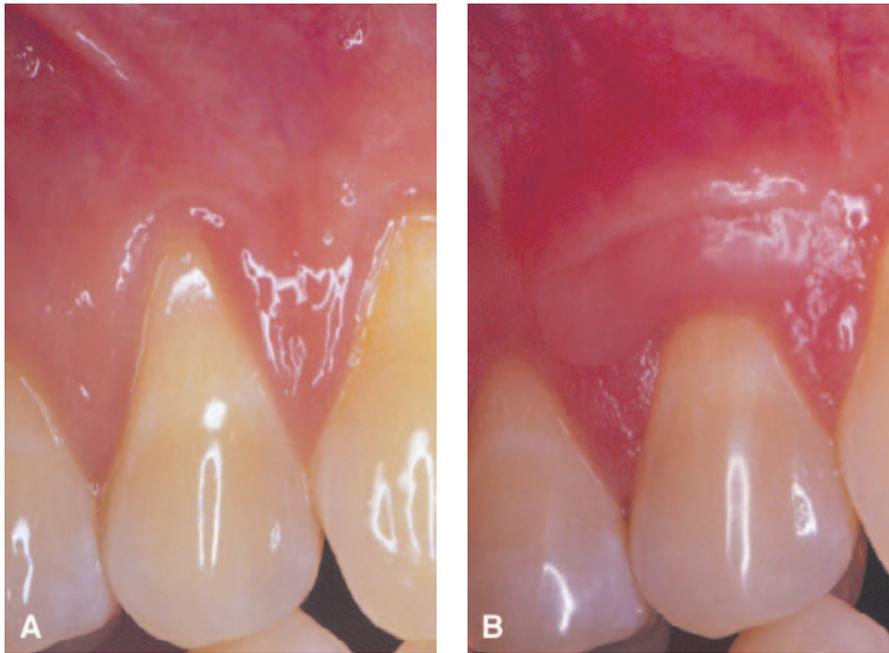


Figure 9.

A) Preoperative photograph of patient # 13's cuspid, which was randomized to receive a subepithelial connective tissue graft (control). **B)** Clinical appearance of the control tooth at 12 months. Note not only the root coverage, but also the increase in keratinized tissue as compared to the preoperative photograph.



Figure 10.

A) Preoperative photograph of patient # 13's cuspid, which was randomized to receive the coronally advanced flap with EMD (test). Note the small amount of keratinized tissue present. **B)** Clinical appearance of the test tooth at 12 months. Note not only the root coverage, but also the increase in keratinized tissue as compared to the preoperative photograph A.

the differentiation of the alveolar mucosa epithelium into keratinized epithelium. In their study, the keratinized tissue width seemed to be related to the presurgical dimensions of the keratinized tissue and the amount of connective tissue left exposed coronal to the flap margin at the end of the surgical procedure. Modica et al.¹⁸ also showed a minimal increase (statistically insignificant) in keratinized tissue that was found following the coronally advanced flap with and without EMD. Our results indicate that the width of the keratinized tissue in the test sites may increase over time reducing the significance of the observation that the control site produced more keratinized tissue. This statement also begs the question, how much keratinized tissue is enough? Although this is a controversial subject, and there is not a certain amount of keratinized tissue that is essential for health, Lang and Löe⁴³ found that sites with ≥ 2 mm keratinized tissue and ≥ 1 mm attached gingiva were healthy. All of the test sites exceeded those dimensions at all time periods following baseline. Although not statistically significant, Figure 3 shows that test sites tended to have less recession over time than control sites. If these trends continue over time, the benefits associated with subepithelial connective tissue grafting, previously unrivaled by other treatment options, may disappear.

Since most root coverage grafts are performed in response to esthetic concerns of the patient, the overall esthetic outcome should be evaluated as the clinician decides which surgical procedure will best meet the needs of the patient (Fig. 2D). Tissue contours and color match are important patient-related outcomes. From a functional viewpoint, an increase in keratinized tissue would generally be thought to be a positive attribute of a procedure. Ideally, this increase should recreate the normal topographical dimensions of the ker-

atinized tissue and the alveolar mucosa, but often the subepithelial connective tissue graft creates a band of keratinized tissue that is much wider and bulkier than normal dimensions found in health. It is not uncommon for the clinician to perform a secondary gingivoplasty of the subepithelial connective tissue graft to reduce its bulk and eliminate surface irregularities. On the whole, treatment with coronally advanced flaps with EMD recreated a more natural appearing mucogingival relationship.

Many teeth that require root coverage grafts have significant root surface abrasion (Figs. 7A and 8A). Subepithelial connective tissue grafts are effective, not only in covering the denuded root surface, but also in reestablishing the proper emergence profile as the tooth surface emerges from the free gingival margin. The connective tissue is trimmed to fit into the abraded root surface in an inlay fashion and the thickness of the graft provides the bulk necessary to recreate a natural looking root eminence (Figs. 7C, 7D, and 7E). EMD is a viscous gel, and it was not known if it could support the coronally advanced flap over severely abraded root surfaces (Fig. 8C) and provide a natural emergence profile and root eminence. The clinical results of this study demonstrated that coronally advanced flaps with EMD can attain those goals (Figs. 8F and 8H), and also achieve a more naturally appearing mucogingival complex as compared to the subepithelial connective tissue graft.

At 1 week there was a notable difference, statistically significant, between the test and control procedures in the healing pattern observed. The healing was categorized by “worse than expected,” “as expected,” or “much better than expected.” At 1 week, the healing observed with the EMD treatment was superior to that observed with the subepithelial connective tissue grafting (Fig. 2B). The clinical finding that wound healing seems faster in the presence of EMD is a frequent comment by those who have used EMD and was reported by Mellonig.⁴⁴ In addition, almost half (45%) of the patients reported great discomfort with the subepithelial connective tissue grafting procedure as opposed to 5% (one patient) with the EMD procedure. The significance of less patient-reported discomfort with the test sites compared to the control sites at 1 week is not surprising. The need for a second surgical site to harvest the connective tissue would obviously lead to more discomfort associated with the control sites. An additional fact not measured, but no less important, is that procuring the connective tissue can be challenging for the clinician especially in patients with thin palatal tissue, with shallow palatal vaults, and with palatal exostoses.

CONCLUSION

There was no significant difference in the percent of root coverage between the test and control group at the end of 12 months, 93.8% of the root surfaces treated with subepithelial connective tissue grafts (control) were covered; whereas, 95.1% of the root surfaces treated with coronally advanced flap plus EMD (test) were covered. Both test and control groups demonstrated an average gain in attachment of 4.5 mm (range 4 to 8 mm). One hundred percent root coverage was obtained 89.5% of the time with the coronally advanced flap with EMD and 79% of the time with the subepithelial connective tissue graft. There were no statistically significant differences in clinical attachment gain, root hypersensitivity, probing depth, or any of the other evaluated parameters with the exception of healing at 1 week, self reported discomfort, and width of keratinized gingiva. Within the limitations of this paper, the results indicate that the addition of EMD to the coronally advanced flap resulted in similar root coverage as compared to the subepithelial connective tissue graft without the morbidity and potential clinical difficulties associated with the donor site surgery.

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