Evaluation of Human Recession Defects Treated With Coronally Advanced Flaps and Either Enamel Matrix Derivative or Connective Tissue: Comparison of Clinical Parameters at 10 Years

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Background: The effective treatment of gingival recession (GR) defects is crucial for predictable outcomes. The most common treatment is the subepithelial connective tissue graft (CTG), but good outcomes have also been obtained using enamel matrix derivative (EMD). A split-mouth, randomized controlled trial was previously performed during a 12-month period to evaluate primary and secondary outcomes in Miller Class I and II GR defects treated with CTG or EMD, both in combination with coronally advanced flap (CAF). The purpose of the current study is to examine the major qualitative and quantitative parameters of this study after a 10-year follow-up.

Methods: Nine of 17 original patients were available for follow-up evaluation 10 years after the original surgery. The parameters measured were: 1) GR depth; 2) probing depth (PD); 3) clinical attachment level; 4) width of keratinized tissue (wKT); 5) percentage of root coverage; 6) root dentin hypersensitivity; 7) color, texture, and contour of treatment sites; and 8) patient satisfaction at 10 years. Results at 1 and 10 years of these nine patients (nine test and nine control teeth) were compared to original baseline values. In addition, results within treatment groups between 1 and 10 years and between treatment groups (i.e., EMD versus CTG) at the same time points were examined.

Results: At 10 years, all quantitative parameters except PD for both treatment protocols showed statistically significant improvements from baseline values, including wKT in the EMD group, which at 1 year was not significantly improved compared with baseline wKT. In addition, at 10 years, there were no statistically significant differences between EMD + CAF and CTG + CAF for any measured parameter. The only statistically significant finding in this study was the difference in wKT found at 1 year (EMD, 3.00 mm; CTG, 3.89 mm; $P = 0.031$). Qualitative parameters at 10 years demonstrated similar stability. The only major qualitative difference was the marginal tissue contour, which was similar to adjacent tissues at EMD-treated sites but greater than adjacent tissues at all CTG sites except one. Esthetically, both EMD- and CTG-mediated treatments were similar at 10 years. However, given the choice, six of nine patients would choose EMD over CTG treatment to avoid a secondary harvesting procedure.

Conclusions: This paper highlights the importance of long-term data as it relates to procedural effectiveness in selecting optimally effective protocols to treat gingival recession. Based on the results of this 10-year follow-up investigation, treatment with either EMD + CAF or CTG + CAF for Miller Class I and II GR defects appears stable, clinically effective, and similar to each other on all measured parameters. *J Periodontol 2012;83:1353-1362.*

KEY WORDS

Case-control studies; connective tissue; enamel matrix proteins; follow-up studies; gingival recession; surgical flaps.

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Gingival recession (GR) defects present both functional and esthetic problems that require effective treatment to achieve long-term positive clinical outcomes. Patient-centered concerns, i.e., esthetic deficiencies, poor plaque control, and chronic dentinal sensitivity, require surgical interventions with minimum operative and postoperative sequelae. Equally challenging, although perhaps more technically elusive, is the regeneration of cementum, inserting periodontal ligament fibers and supporting alveolar bone across all categories of GR defects.[1] A number of recent systematic reviews have reviewed multiple therapeutic approaches to GR defects, including coronally advanced flap (CAF) alone and in combination with subepithelial connective tissue graft (CTG), guided tissue regeneration (GTR), enamel matrix derivative (EMD), and acellular dermal matrix (ADM).[2-7] Although alternative approaches to CTG + CAF appear effective when examining specific clinical parameters, much of the current literature suggests that only CTG + CAF appears consistently effective across all clinical efficacy endpoints, especially stability of root coverage over time.[2-10] Objective evidence, however, suggests limited ability of CTG + CAF to regenerate missing cementum, inserting connective tissue fibers and supporting alveolar bone. Although a number of studies refer to the ability of CTG + CAF to effect a limited degree of periodontal regeneration, most suggest healing through a long junctional epithelium or through connective tissue adaptation with adjacent root surfaces.[11-15]

Although it is considered by many to be the gold-standard treatment for root coverage, CTG has a number of disadvantages: 1) a secondary harvesting surgery for donor tissue is required; 2) increased morbidity may be associated with the donor surgery; and 3) a limited amount of donor tissue is available, limiting the number of defect sites treated per patient visit.[16,17] As a result of these disadvantages, along with the variability in effecting true periodontal regeneration, alternatives to CTG continue to be sought.[10,18-23] EMD in combination with CAF may provide a viable clinical alternative to CTG, including regeneration of tissues of the attachment apparatus.[24-30]

A number of recently published systematic reviews include randomized controlled trials (RCTs) examining EMD + CAF efficacy endpoints in treating GR.[4-6] A systematic review by Cheng et al.[5] found that clinical attachment level (CAL), residual GR depth, and percentage root coverage were statistically significantly better for EMD + CAF than for CAF alone or CAF + chemical root surface conditioning at 6 and 12 months (P<0.001). In a Cochrane Systematic Review by Chambrone et al.[6] examining Miller Class I and II defects, data from the included RCTs showed mean root coverage for CTG + CAF from 84.0% to 95.1% versus 55.9% to 86.7% for EMD + CAF. Complete root coverage varied from 18.1% to 86.7% for CTG-mediated treatment and from 53.0% to 89.5% for EMD + CAF. Follow-up times ranged mainly from 6 to 12 months, with three studies extending to 2 years. A systematic review by Cairo et al.[4] examined complete root coverage as the primary outcome variable, concluding that both CTG or EMD in combination with CAF procedures increased the probability of complete root coverage and reduced GR in Miller Class I and II defects. In addition, both CTG and EMD procedures in combination with CAF led to better keratinized tissue (KT) gains than CAF alone. The majority of included RCTs extended up to 12 months, with four studies extending to 2 years.[4]

In a split-mouth RCT, McGuire and Nunn[24] examined treatment outcomes related to either CTG + CAF or EMD + CAF treatment protocols for Miller Class I and II defects in 17 patients during a 12-month period. In this study, each patient served as his/her own control. The results indicated that the combination of EMD + CAF was equally as effective as CTG + CAF for all measured parameters except early healing, self-reported discomfort, and gains in KT. The addition of EMD, without the need for donor surgery, led to earlier healing and less reported discomfort, whereas CTG sites tended to regenerate more KT. Within each group, however, the gains in KT were statistically significant from baseline. Average gains in root coverage were the same for both groups (4.5 mm; range: 4 to 8 mm). Mean percentages of root coverage for both groups were not significantly different (CTG: 93.8%; EMD: 95.1%; P= 0.82), nor were rates of 100% root coverage at 12 months (CTG: 79%; EMD: 89.5%). CAL gains, probing depths (PDs), and root sensitivity were not significantly different between the CTG and EMD sites.

Systematic reviews of GR-related RCTs require a minimum follow-up duration of 6 months after surgery for study entry. Longer follow-up times are preferred and generally extend an additional 6 months, although RCTs extending to 24 months are occasionally available for inclusion in the reviews. To the best of our knowledge, except for one reported RCT by Nickles et al.[31] comparing GTR- to CTG-mediated treatment and a 14-year follow-up split-mouth trial examining CAF with two different methods of root surface modification,[32] no additional case series study or RCT examining treatment efficacy for GR has ≥10-year follow-up duration from the time of the original surgery. The purpose of the current study is to examine the major qualitative and quantitative parameters of the McGuire and Nunn[24] GR study 10 years after original treatment with either CTG + CAF or EMD + CAF.

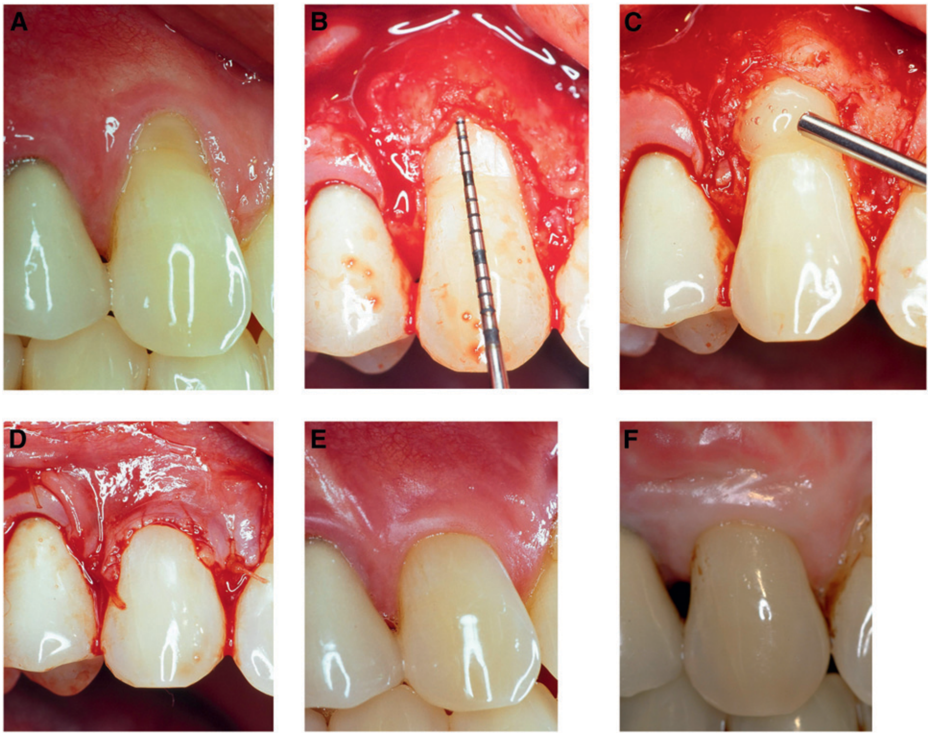

Figure 1.
Patient 20. ***A)*** *At baseline, a maxillary cuspid randomized to receive test (EMD) treatment.* ***B)*** *Intraoperative measurements after full-thickness flap elevation beyond the mucogingival junction.* ***C)*** *EMD applied to the root surface.* ***D)*** *Mucogingival flap coronally advanced to the level of the CEJ and secured with sutures.* ***E)*** *A 12-month follow-up, test site with no evidence of GR.* ***F)*** *A 10-year follow-up, test site with no GR and an increase of 4 mm of KT from both baseline and 12 months. (This patient received virtually no maintenance care after the completion of the initial study.)*

MATERIALS AND METHODS

Study Population

Of 17 patients completing the original study, nine were available for follow-up 10 years after the original surgery. The 18 evaluated teeth were distributed among incisors, cuspids, and bicuspids. The follow-up patient population, ranging from 44 to 74 years of age (mean age: 55.4 years), included four males and five females and was 100% white. Seven never smoked, and two had not smoked for 39 years. Of the nine patients, five had no reported medical problems, whereas four reported generalized anxiety-related symptoms.

Patient Population Lost to Follow-Up

Eight of the original 17 patients were lost to follow-up. Two patients chose not to participate, and two could not be contacted. Of the remaining four patients, one fractured the test tooth and had it removed, two patients had the test and control teeth prosthetically crowned for reasons other than residual recession, and one patient had multiple teeth with deep abfractive lesions restored, including the test and control teeth. In each of the latter three patients, the measurement reference points (cemento-enamel junction [CEJ]) used at baseline were no longer present, preventing the possibility of quantitative 10-year follow-up data. For each of the four known patients in this group, there was no evidence that dental restorative therapy was required to compensate for residual or worsening gingival recession. Overall, loss to follow-up was a random event unrelated to treatment or outcomes so that the only problem presented was a reduction in sample size.

Summary of Original Surgery

Surgical protocol for test treatment with CAF + EMD. After root preparation, a sulcular incision was made at the recession site and extended horizontally into the adjacent interdental regions. Bilateral vertical releasing incisions, connected to the horizontal incision, were extended out into the lining mucosa and a full-thickness mucoperiosteal flap elevated until the mucogingival junction was passed (Figs. 1A and 1B). The periosteum was then cut, followed by blunt dissection into the vestibular lining mucosa to eliminate muscle tension. The facial aspects of the interdental papillae were de-epithelialized, creating a connective tissue bed for suturing the CAF.

The exposed root surface was then conditioned with 24% EDTA‡ for 2 minutes, rinsed with saline, and then dried. EMD§ was then applied onto the root surface and the mucoperiosteal flap coronally advanced to the level of the CEJ and sutured to the de-epithelialized papillae (Figs. 1C and 1D).

Surgical protocol for control treatment with CAF + CTG. The control procedure was identical to the test procedure, with the following exceptions: 1) a partial-thickness mucosal flap was developed in lieu of a full-thickness mucoperiosteal flap; and 2) a subepithelial CTG from the premolar region of the palate was obtained and secured over the denuded root surface in lieu of placement of EMD (Figs. 2A and 2B). As in the test group, the mucosal flap was passively coronally advanced to the level of the CEJ. Postoperative oral hygiene instructions designed to

‡ PreGel, Straumann, Andover, MA.
§ Emdogain, Straumann.

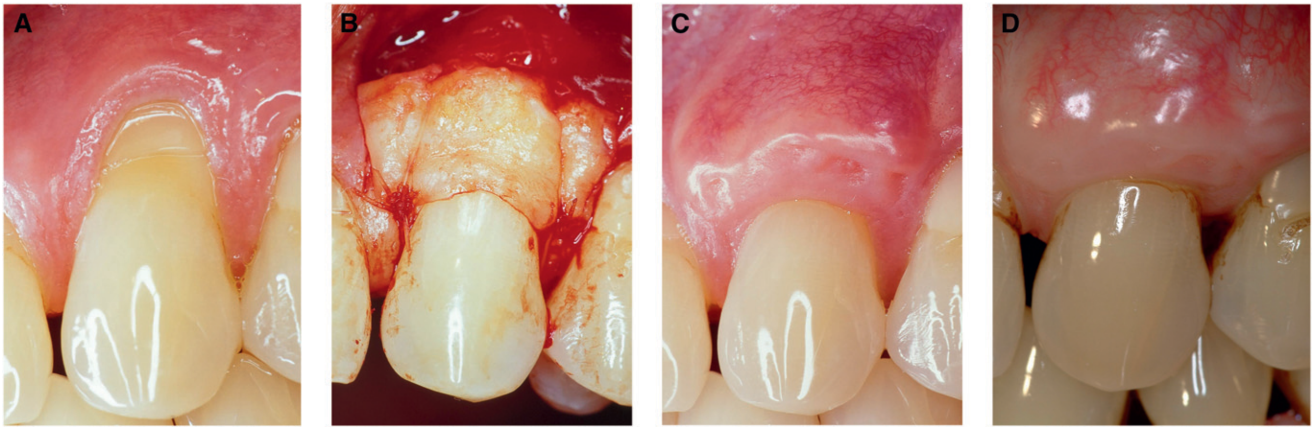

Figure 2.
Patient 20. ***A)*** *At baseline, the contralateral cuspid randomized to receive control (CTG) treatment.* ***B)*** *Subepithelial CTG (control) is sutured over the denuded root surface.* ***C)*** *A 12-month follow-up, control site with no evidence of recession and a 4-mm increase in KT.* ***D)*** *A 10-year follow-up, control site with no change in GR or KT. (This patient received virtually no maintenance care after the completion of the initial study.)*

minimize trauma at the gingival margins were given, and the patients were examined 1 week after surgery and at months 1, 2, 3, 6, 9, and 12.

Clinical Evaluation 10 Years After Original Surgery

As performed for the original RCT 10 years earlier, the treated sites were clinically examined, the measurements were recorded, and clinical photographs were taken. The same examiner (Carol Waring, RDH, PerioHealth Professionals, Houston, Texas) who recorded the original study measurementswas still maskedand performed the follow-up 10-year examinations after being recalibrated for measurement accuracy and consistency. The primary efficacy parameter was the change in the depth of the recession defect. Secondary efficacy parameters included the following: 1) PD; 2) CAL; 3) keratinized tissue width (wKT); 4) percentage of root coverage; 5) root dentin hypersensitivity; 6) clinician rating of color (compared to adjacent tissue), texture (compared to adjacent tissue), and contour (compared to adjacent tissue) of treatment sites; and 7) patient satisfaction at 10 years.

At baseline, there were no significant differences observed between test and control sites. Recession depth, using a periodontal probe,‖ was measured from the CEJ to the free gingival margin. A periodontal probe¶ measured mid-buccal PD from the gingival margin to the base of the defect. CAL was measured mid-buccal from the CEJ to the base of the defect. wKT measurements, measured with a periodontal probe,# extended from the free gingival margin to the mucogingival junction.

Qualitative efficacy parameters were assessed as follows. Root dentin hypersensitivity was assessed using a conventional blast of air for 3 seconds at the exposed root surface. The hypersensitivity was recorded as present (yes) or not present (no). Gingival color, texture, and contour were assessed by comparing test and control grafts to surrounding tissues and scoring through questionnaires, i.e. more red, less red, equally red; more firm, less firm, or equally firm; or more contour, less contour, or equal contour.

Patient satisfaction at 10 years was assessed by responses to the following two questions: 1) Which procedure do you prefer to correct your gum recession, the procedure with the EMD or the CTG and why? and 2) Are you equally satisfied with the esthetic results of the two sites treated or are you more satisfied with one treated site versus the other?

Statistical Methods

Qualitative measures, including root hypersensitivity, soft-tissue color (compared to adjacent tissue), soft-tissue texture (compared to adjacent tissue), and soft-tissue contour (compared to adjacent tissue), were dichotomized for statistical analysis. Specifically, root hypersensitivity was dichotomized into "yes" or "no," indicating that either there was root hypersensitivity present or there was no root hypersensitivity present. Soft-tissue measures were dichotomized into either "equal" (i.e., equivalent to adjacent tissue) or "not equal" (i.e., not equivalent to adjacent tissue). McNemar test for paired dichotomous outcomes was used to test for differences in qualitative outcomes between control and test sites.

Within-treatment comparisons across time and between-treatment comparisons at each point in time were made using non-parametric tests. Likewise, all

‖ UNC-15 periodontal probe, Hu-Friedy, Chicago, IL.
¶ Florida periodontal probe, Florida Probe Corp., Gainesville, FL.
\# UNC-15 periodontal probe, Hu-Friedy.

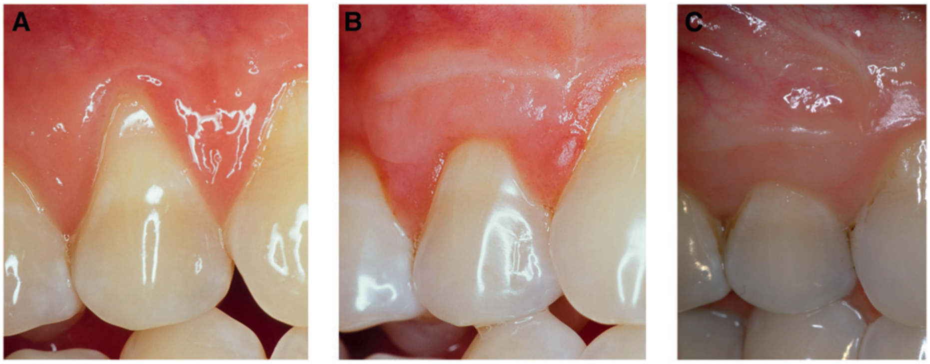

Figure 3.
Patient 13. ***A)*** At baseline, a bicuspid site randomized to receive control (CTG) treatment. ***B)*** A 12-month follow-up after CTG. There has been a 1-mm increase in KT from baseline. Mild marginal inflammation present. ***C)*** The results at 10 years after CTG remain the same as at 12 months.

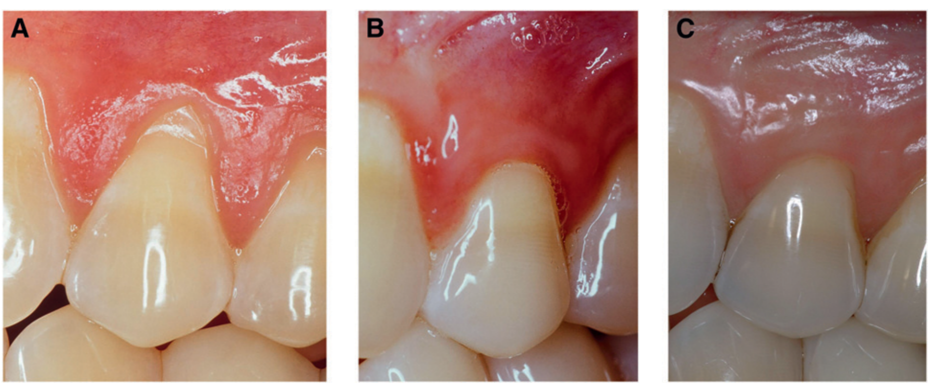

Figure 4.
Patient 13. ***A)*** At baseline, the contralateral bicuspid randomized to receive test (EMD) treatment. ***B)*** A 12-month follow-up with no recession and 2 mm of wKT. ***C)*** At 10 years after EMD treatment, there is no GR evident and no increase in KT from baseline and 12 months.

change comparisons (baseline versus 1 year and baseline versus 10 years) both within and between treatments were made using non-parametric tests. In particular, for continuous outcomes (recession depth, PD, CAL, wKT, and percentage root coverage), a (paired) Wilcoxon signed-rank test was used. For the binary outcome of patients with 100% root coverage versus those without 100% root coverage, Fisher's exact test comparing two binomial proportions was used.

RESULTS

Ten-Year Assessment of Qualitative Parameters

At 10 years after the original surgeries, clinical photos were taken and a number of qualitative parameters were examined (Figs. 1F, 2D, 3C, and 4C). (To avoid selection bias, only those grafted site images included in the McGuire and Nunn[24] publication are included here. Note that patient 13, Figures 9 and 10, of the study by McGuire and Nunn had incorrect tooth designation. Instead of maxillary cuspids, bicuspid sites were originally grafted. This error has been corrected here.) Moderate root dentin hypersensitivity continued to exist in a minority of the test (n = 3) and control (n = 1) sites, although the majority of sites exhibited no sensitivity to a conventional 3-second blast of air to the root surface. Although control sites tended to be less likely to exhibit root hypersensitivity compared to test sites (one of nine control sites with root hypersensitivity versus three of nine test sites with root hypersensitivity), the difference between test and control sites failed to achieve statistical significance ($P = 0.157$). Test sites were more likely to exhibit equivalent texture to surrounding tissues compared to control sites (eight of nine test sites with equivalent texture to surrounding tissues versus five of nine control sites with equivalent texture to surrounding tissues), although the difference falls short of achieving statistical significance ($P = 0.083$). When examining color equivalence of the surgical sites to adjacent tissues, eight of nine test sites and six of nine control sites were judged to have equivalent color to surrounding tissues, although this difference between test and control sites failed to achieve statistical significance ($P = 0.157$). For equivalence of tissue contour, test sites were found to be significantly superior, with eight of eight test sites having equivalent tissue contour to adjacent tissue, whereas only one of eight control sites had equivalent tissue contour to adjacent tissue ($P = 0.008$).

Ten-Year Assessment of Quantitative Parameters

Mean differences in quantitative clinical measures between control and test sites were not significantly different from zero at baseline. Similarly, mean differences in quantitative clinical measures between control and test sites were not significantly different from zero at 1 and 10 years, with the exception of wKT, in which control sites yielded significantly greater wKT

Table 1.

Change From Baseline and Change Between 1 and 10 Years (N = 9 Patients, 18 Teeth)

Parameter	Baseline Mean ± SD (Minimum, maximum)	Change Between Baseline and 1-Year Mean ± SD (Minimum, maximum)	*P* for Baseline to 1-Year Change	Change Between Baseline and 10- Year Mean ± SD (Minimum, maximum)	*P* for Baseline to 10-Year Change	Change Between 1- and 10-Year Mean ± SD (Minimum, maximum)	*P* for 1- to 10-Year Change
GR depth (mm)							
CTG	4.00 ± 0.50 (3, 5)	3.89 ± 0.78 (2, 5)	0.004*	3.67 ± 1.12 (1, 5)	0.004*	−0.22 ± 0.44 (−1, 0)	0.500
EMD	4.00 ± 0.00 (4, 4)	3.78 ± 0.44 (3, 4)	0.004*	3.33 ± 0.87 (2, 4)	0.004*	−0.44 ± 0.53 (−1, 0)	0.125
P for CTG versus EMD			1.000		0.625		0.500
PD (mm)							
CTG	1.67 ± 0.71 (1, 3)	−0.22 ± 0.97 (−1, 2)	0.750	−0.11 ± 0.93 (−1, 2)	1.000	0.11 ± 0.33 (0, 1)	1.000
EMD	1.67 ± 0.71 (1, 3)	0.33 ± 0.71 (−1, 1)	0.375	0.22 ± 0.97 (−1, 2)	1.000	−0.11 ± 1.05 (−2, 1)	1.000
P for CTG versus EMD			0.234		0.563		0.750
CAL (mm)							
CTG	5.67 ± 0.87 (5, 7)	3.67 ± 1.22 (2, 6)	0.004*	3.56 ± 1.24 (1, 5)	0.004*	−0.11 ± 0.60 (−1, 1)	1.000
EMD	5.67 ± 0.71 (5, 7)	4.11 ± 0.78 (3, 5)	0.004*	3.56 ± 1.42 (2, 6)	0.004*	−0.56 ± 1.42 (−1, 3)	0.391
P for CTG versus EMD			0.531		1.000		0.344
wKT (mm)							
CTG	2.56 ± 0.73 (2, 4)	1.33 ± 0.87 (0, 2)	0.016*	1.44 ± 0.73 (0, 2)	0.008*	0.11 ± 1.05 (−2, 2)	1.000
EMD	2.67 ± 0.71 (2, 4)	0.33 ± 0.50 (0, 1)	0.250	0.89 ± 1.27 (−1, 3)	0.125	0.56 ± 1.13 (−1, 3)	0.313
P for CTG versus EMD			0.047*		0.359		0.313

All *P* values are obtained from the Wilcoxon signed-rank test.
* Statistically significant.

at 1 year compared to wKT for test sites at 1 year (mean wKT for CTG, 3.89 mm; mean wKT for EMD, 3.00 mm; $P = 0.031$). Within-group comparisons were made to test whether any clinical measures had changed significantly from 1 to 10 years for each group. Using Wilcoxon signed-rank test, no significant change from 1 to 10 years for any clinical measure for either group was noted.

GR depth, average percentage root coverage, and percentage with 100% root coverage. The primary efficacy endpoint of this study was change in recession depth. At both 1 and 10 years, significant improvements compared with baseline were achieved for both test and control sites, with mean test reductions of 3.78 and 3.33 mm ($P_{1\ year} = 0.004$ and $P_{10\ years} = 0.004$) and mean control reductions of 3.89 and 3.67 mm ($P_{1\ year} = 0.004$ and $P_{10\ years} = 0.004$) at 1 and 10 years, respectively (Table 1). However, no statistically significant differences in GR depth changes were noted between test and control sites from 1 to 10 years ($P = 0.500$) (Table 1). This lack of statistical significance is further demonstrated by the finding that mean GR depths at 1 and 10 years for control and test treatments were significantly improved from baseline, yet exhibit no intragroup or intergroup statistically significant differences in mean values at either time point. Statistically, at both 1 and 10 years, recession depth results were not significantly different for either treatment modality and appear stable with time.

Percentage of root coverage for control and test sites was evaluated. No significant differences in mean percentage root coverage were found between the control sites (96.3% ± 11.1% and 89.8% ± 22.7%; $P = 0.500$) at 1 and 10 years, respectively, nor were any significant differences noted between test sites at 1 and 10 years (94.4% ± 11.0% and 83.3% ± 21.7%; $P = 0.125$). At both 1 and 10 years, the mean percentage root coverage was not significantly different between test and control sites ($P = 1.00$ at 1 year and $P = 0.500$ at 10 years) (Table 2).

The percentage of patients with 100% root coverage was not significantly different at 1 and 10 years within and across test and control sites. Control sites at 1 and 10 years demonstrated 88.9% and 77.8%

Table 2.

Percentage Root Coverage

	1-Year Mean ± SD (Minimum, maximum)	10-Year Mean ± SD (Minimum, maximum)	*P* Between 1 and 10 Years
Average % root coverage			
CTG	96.3 ± 11.1 (66.7, 100)	89.8 ± 22.7 (33.3, 100)	0.500
EMD	94.4 ± 11.0 (75, 100)	83.3 ± 21.7 (50, 100)	0.125
CTG – EMD	1.9 ± 17.1 (−33.3, 25)	6.5 ± 28.2 (−41.7, 50)	0.500
P for mean difference	1.000	0.500	
% Patients with 100% coverage			
CTG	88.9	77.8	0.317
EMD	77.8	55.6	0.157
P	0.564	0.157	

P values are obtained using Wilcoxon signed-rank test for average percentage root coverage and McNemar test comparing correlated patients with 100% coverage.

complete root coverage (P = 0.317), respectively, whereas test sites demonstrated 77.8% and 55.6% complete root coverage (P = 0.157), respectively. Comparison between test and control sites at 1 and at 10 years showed no statistically significant differences between either treatment modality (P = 0.564 at 1 year and P = 0.157 at 10 years). Two additional patients with <100% root coverage in the test group compared to the control group accounted for the difference in percentage with 100% root coverage seen at 10 years (Table 2).

PD, CAL, and KT. Secondary efficacy parameters included PD reduction, changes in CAL, and wKT. Mean PD values as well as PD changes both within and across test and control sites at all time points demonstrated no statistically significant differences. Compared with mean baseline values, there were also no significant differences at 1 and 10 years for both test and control sites. In addition, no differences were seen when comparing within and across test and control sites at both 1 and 10 years (Table 1).

Significant changes in CAL compared to baseline were observed at both 1 and 10 years for both test and control sites (P = 0.004 at 1 and 10 years) (Table1); however, there were no significant intragroup differences from 1 to 10 years and no significant differences between the groups at either time point (Table 1).

Comparisons in both mean wKT values and mean changes in wKT at 1 and 10 years are noted in Table 1. Significant increases in wKT between baseline and 1 year are seen for control sites (P = 0.016), but there were no significant changes from baseline to 1 year at test sites (P = 0.250) (Table1). Mean wKT values were significantly greater at control versus test sites at 1 year (3.89 versus 3.00 mm, P = 0.031), but the difference was not significant after 10 years (P = 0.359). Mean wKT values at 10 years were 4.00 and 3.56 mm for control and test sites, respectively.

Post hoc power analysis. For GR, this study has 84% power to detect a 0.5-mm difference in change in recession from 1 to 10 years between the two treatment groups for a two-tailed test at 0.05 level of significance. For percentage root coverage, there is 60% power to detect a 10% difference in change in percentage root coverage from 1 to 10 years between the two treatment groups for a two-tailed test at 0.05 level of significance. There is also 66% power and 67% power to detect a 10% reduction in percentage root coverage from 1 to 10 years for the control group and test group, respectively. For wKT, the current study has 32% power to detect a 0.5-mm difference in change in wKT from 1 to 10 years between the two treatment groups and 84% to detect a 1.0-mm difference in change in wKT from 1 to 10 years between the two treatment groups, both powers for a two-tailed test at 0.05 level of significance.

Ten-year assessment of procedure choice and esthetic satisfaction. At 10 years, patients were asked to respond to questions related to procedure preference and esthetic satisfaction. Six of the nine patients favored the test treatment, one favored the control treatment, and two had no preference (P = 0.059). When assessing esthetic satisfaction, six patients had no preference for a particular type of treatment, two favored esthetic results with the test treatment, and one favored results with the control treatment (P = 0.564).

DISCUSSION

Long-term data related to procedural effectiveness are critical to choosing optimally effective gingival recession treatment protocols. At issue, however, is the definition of "long-term." Multiple systematic reviews of RCTs provide valuable evidence-based data to clinicians confronted with challenging GR defects.[2-7] As noted previously, a minimum study duration of 6 months is required for inclusion in systematic reviews, with an additional 6 months more often the norm.[2-7] Longer study durations ≥2 years are occasionally included in systematic reviews devoted to GR defects.[2,4,6] A number of individually reported studies that extend beyond 2 years emphasize the importance of long-term follow-up in assessing treatment effectiveness with time.

Harris[33], in a retrospective analysis of 25 patients treated with either subepithelial CTG or ADM** for GR defects, examined two time points after grafting: 12.3 to 13.2 weeks or 48.1 to 49.2 months. Short-term results revealed no significant differences between both treatment types on most parameters, especially percentage root coverage (CTG, 96.6%; ADM, 93.4%). Long-term results, however, revealed a statistically significant difference in root coverage between ADM- and CTG-treated sites (ADM, 65.8%; CTG, 97.0%). Connective tissue–grafted sites remained stable with time, whereas ADM-grafted sites exhibited significant breakdown at 4 years. Interestingly, a previous study examining ADM-grafted GR sites at 12 and 18.6 months showed no significant difference in percentage root coverage for the early (91.7%) and later (87.0%) time points, suggesting the possible need to reexamine criteria defining ''long-term'' follow-up.[34]

In the only trial comparable to the current study examining procedural effectiveness over a 10-year duration for GR defects, Nickles et al.[31] observed the importance of time in affecting treatment results between CTG and GTR in conjunction with CAF. Although both therapies resulted in significantly greater root coverage at 6 months compared to baseline, greater root coverage was only maintained in the CTG group by 12 months. However, from 6 months to 10 years, significant changes in both approaches to GR treatment occurred, with mean relative CTG root coverage reduced from 72.7% to 43.7% and GTR root coverage reduced from 43.7% to 1.9%. Although treatment results declined for both modalities during the 10-year period, the GTR decline was statistically significantly and clinically more severe. These findings are in stark contrast to the current study in which there were no significant differences in percentage root coverage between 1 and 10 years, and the amount of root coverage remaining at 10 years was at the higher end of the range published in systematic reviews[2-5] for root coverage expected at 6 months to 2 years. In the current study, both groups maintained average percentage root coverage >80% with 60% power to detect a 10% difference in change in percentage root coverage from 1 to 10 years between the two treatment groups for a two-tailed test at the 0.05 level of significance. Although the EMD group had 55.6% with 100% root coverage at 10 years compared to the CTG group with 77.8% having 100% root coverage at 10 years, the minimum root coverage for the EMD group was 50%, whereas the minimum root coverage for the CTG group was 33%.

In a similar but longer term 14-year randomized split-mouth study, Pini-Prato et al.[32], with the same number of patients as the current study, examined outcomes of two different methods of root surface modification (root surface polishing [test] versus root planing [control]) in combination with CAF. For both groups, recession increased slightly with time (≈0.024 mm/year), whereas the amount of KT decreased slightly during the 14-year period. There was, however, a significant interaction between baseline KT and surface modification type. Root surface polishing resulted in greater GR reduction with greater baseline wKT, whereas root planing exhibited greater GR reduction in sites with smaller baseline wKT, divergent results unable to be explained at the present time. As in the current study, a post hoc power calculation was performed. Although limited to nine individuals, Pini-Prato et al.[32] had 67% power to detect a difference in change of 0.5 mm at a significance level of $\alpha = 0.05$.

The current study examined 10-year results on the major qualitative and quantitative parameters from a previously reported 12-month study[24] examining treatment effectiveness between CTG + CAF and EMD + CAF for GR defects. Unlike the study by Nickles et al.[31], however, the split-mouth design of the current study allowed each patient to serve as his/her own control. Results for all parameters for both test and control sites were consistently stable with time. Except for PD reduction (both groups) and wKT at 1 year (test group), quantitative results for all sites at both 1 and 10 years were significantly improved from baseline. Importantly, both within-group and across-group comparisons from 1 to 10 years revealed no statistically significant differences. Except for wKT in the test group, there was little variation in parameter values for either group during the 10-year interval. Treatment with either EMD + CAF or CTG + CAF for recession defects therefore showed similar effectiveness after 10 years.

Of particular interest to both this and other studies are the possible long-term effects GR treatment protocols have on KT. In a 5-year follow-up study of CAF alone in treating 73 Miller Class I and II GR defects, Zucchelli and De Sanctis[35] found statistically and clinically significant increases in wKT. At baseline, 38% of the recession sites had ≤1 mm wKT. At 5 years, 92% of the treated teeth had ≥3 mm of KT and none had <2 mm of KT. According to the authors, the mucogingival junction, displaced coronally during recession surgery, appears to shift apically toward its

** AlloDerm, Biohorizons, Birmingham, AL.

presurgical position for ≥5 years, confirming the hypothesis that the location of the mucogingival line is genetically determined.[35,36] In contrast, Pini-Prato et al.[32] at 14 years after CAF found slightly decreased amounts of KT regardless of the type of root modification initially used. In comparing CAF alone to CAF in combination with other therapeutic modalities, in a systematic review, Cairo et al.[4] found better outcomes in KT gain when CTG or EMD were used in conjunction with CAF. Comparison between CAF + CTG versus CAF (two RCTs included) led to a mean KT difference of 0.73 mm (P = 0.0001). Comparison between CAF + EMD versus CAF (five RCTs included) led to a mean KT difference of 0.42 mm (P = 0.0007), in favor of the combination treatment.

In the current study, at 1 year there was no significant difference in change of wKT from baseline (P = 0.250) in the test group compared to the significant increase in wKT in the control group at 1 year, leading to a significant difference between the groups. However, there was no statistically significant difference between the groups at 10 years, because both groups had continued to regenerate additional KT and showed significant additions of KT from baseline. This increase in wKT to a similar level with CTGs is particularly interesting given that the majority of studies with follow-up durations <10 years, although demonstrating increases in KT for EMD-mediated procedures, tend to demonstrate quantitatively greater mean values of KT for CTGs.[4,24,25,35] Data from the current study alone cannot explain why the test group demonstrated increased KT at 10 years versus 1 year, suggesting the need for additional study. This result does, however, reiterate time as an important factor in determining the fate of regenerative procedures.

Equally important to the quantitative results were the qualitative findings of patient-centered parameters examined in the current study. Although some root sensitivity continued to exist in a minority of patients for both groups, this was no longer a cause for concern for the majority of patients. Moreover, at 10 years the difference between test and control sites failed to achieve statistical significance (P = 0.157). The three additional qualitative parameters compared 10-year test and control sites to adjacent tissues and therefore contributed to patients' perceptions of esthetics at the test and control sites. In general, sites in both groups compared favorably to texture, color, and contour at adjacent tissues, parameters clearly important for self-assessment of the esthetic result. The only major qualitative difference between test and control sites was an increase in overall contour of the control sites compared to adjacent tissues, whereas the test sites were judged to have equal contour compared to adjacent tissues. When examining patient esthetic satisfaction and procedure preference at 10 years, both procedures appeared to yield equally satisfying esthetic results to the majority of the patients. However, when given the choice of procedure, two-thirds of the patients preferred the test over the control treatment to avoid the need for a secondary harvesting procedure.

CONCLUSIONS

Although 10-year follow-up data are clearly important and shed light on the importance of time as a significant determinant of procedure stability and effectiveness, the number of patients lost to follow-up presents a particularly difficult problem, especially given the small initial sample size of most dental studies. In this study, eight of 17 patients were unavailable for 10-year data acquisition, clearly a substantial number that could have led to different long-term qualitative and quantitative results. Nevertheless, patient loss appeared unrelated to treatment outcomes, and a post hoc power analysis for each outcome parameter suggested sufficient power to allow meaningful statistical and clinical interpretation of the current data. The trends for the outcome variables examined in this study indicate long-term stable results for both EMD and CTG treatment protocols for GR defects, especially when compared to baseline, as well as greater similarity between EMD- and CTG-treated sites when examined a decade after initial surgery.

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