

# Long-Term Results Comparing Xenogeneic Collagen Matrix and Autogenous Connective Tissue Grafts With Coronally Advanced Flaps for Treatment of Dehiscence-Type Recession Defects

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**Background:** Although connective tissue grafts with coronally advanced flaps (CTG + CAF) have been deemed the gold standard for recession defect treatment, to provide adequate recession coverage, the periodontal profession continues to pursue lower-morbidity, patient-preferred substitutes that are more convenient and of unlimited supply.

**Methods:** Using a randomized, controlled, and masked contralateral comparison of matched-pair, within-patient recession defects, collagen matrix (CMX) + CAF therapy was compared with CTG + CAF at 6 months and 5 years. The primary efficacy endpoint was percentage of root coverage (RC). Secondary efficacy parameters included width of keratinized tissue (KTW), probing depth (PD), clinical attachment level (CAL), clinician rating of color and texture compared with surrounding tissues, and patient esthetic satisfaction.

**Results:** Seventeen patients were available for the 5-year recall. Mean RC between 6 months and 5 years changed from 89.5% to 77.6% for CMX + CAF test sites and 97.5% to 95.5% for CTG + CAF control sites. KTW averaged >3 mm for both test and control sites at 5 years. PD was equivalent at all time points. The 6-month to 5-year changes for RC, KTW, and PD were not significantly different between therapies. CAL change from 6 months to 5 years was greater for CTG + CAF (0.26 mm) than CMX + CAF (−0.21 mm). Tissue color match to surrounding tissues remained similar for both therapies throughout the study. There was a difference in tissue texture at both 6 months and 5 years, with CMX + CAF sites tending to be “equally firm” and CTG + CAF sites “more firm.” Patient satisfaction was high, with no statistical difference in satisfaction between therapies at any time point.

**Conclusion:** When balanced with patient-reported satisfaction, clinical rankings of esthetics, and control and historical RC results reported by other investigators, CMX + CAF appears to present a viable and long-term alternative to traditional CTG + CAF therapy. *J Periodontol* 2016;87:221-227.

## KEY WORDS

Biocompatible materials; collagen; connective tissue; gingival recession tissue grafts; tissue engineering.

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In traditional recession defect studies and systematic reviews, root coverage (RC) results have been reported at 6 months to 1 year, and sometimes 2 years.<sup>1</sup> Longer-term monitoring would be appropriate for better certainty of patient prognosis, particularly when studying new techniques and biomaterials. The 2008 European Workshop on Periodontology concluded that long-term results of  $\geq 5$  years are needed to evaluate the stability of clinical outcomes.<sup>2</sup> Because an autograft, particularly a subepithelial connective tissue graft under a coronally advanced flap (CTG + CAF), appears to be the gold standard for recession coverage,<sup>3</sup> and results are maintained fairly well long-term, CTG + CAF tends to be the standard against which new therapies are tested.<sup>4</sup>

The authors' practice-based research center has investigated several CTG harvest alternatives.<sup>5,6</sup> To provide adequate recession coverage, researchers continue to pursue lower-morbidity, patient-preferred substitutes that are more convenient and of unlimited supply. The authors' research has conformed to a particular study model: randomized, controlled, and masked contralateral comparison of matched-pair, within-patient recession defects. Many study patients have been enrolled from the maintenance population of patients, so long-term recalls and evaluation of long-term results are possible.

In 2007, the authors initiated a study of what was then a new harvest graft alternative: a xenogeneic collagen matrix<sup>†</sup> (CMX).<sup>7</sup> CMX is a bilayered composite of pure Type I and III porcine collagen. The outer, more compact layer is designed to hold sutures and protect the defect in case of exposed healing. The inner and more porous matrix layer is designed to promote quick stabilization of the blood clot and encourage rapid vascularization and tissue integration<sup>8,9</sup> (Fig. 1).

After the design of a traditional, practice-based recession study model, CTG + CAF and CMX + CAF were

compared in contralateral, matched-pair, within-patient recession defects. After 5 years, the authors recalled these patients to evaluate long-term results.

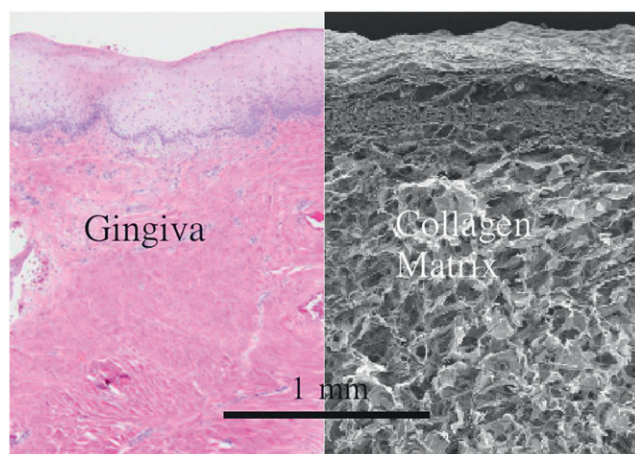
## MATERIALS AND METHODS

The authors' original 2007 study (single-masked, randomized, controlled, split-mouth study) involved 25 patients each with two sites exhibiting comparable Class I or II recession defects in contralateral quadrants of the maxilla or mandible. The details of the surgical procedure can be found in the original publication.<sup>7</sup> In brief, the exposed portions of the roots were prepared using chisels, curets, and finishing burs, as needed. Intra-crevicular incisions were made to mobilize partial-thickness mucosal flaps and were extended to involve the papilla regions on either side of the teeth. Vertical releasing incisions, extending from the papilla out into the lining mucosa, were placed at each side of the teeth to facilitate repositioning of the flap tissue over the exposed root surface. Partial-thickness flaps were elevated apically until the mucogingival line had been passed, and the periosteum was then cut. A blunt dissection into the vestibular lining mucosa was carried out to eliminate muscle tension so that the mucosal flaps could be passively positioned at or slightly above the level of the cemento-enamel junction (CEJ). The facial portion of the interdental papilla was de-epithelialized, creating a connective tissue bed to which the CAF could later be sutured, and further instrumentation of the previously exposed root surfaces was carried out as necessary. The exposed root surfaces were conditioned with EDTA.

CMX test biomaterial was cut to exact size and placed over the dehiscence defects, sutured to the interdental papillae, and covered with CAFs. The tissue flaps were sutured in an interrupted fashion to the de-epithelialized papilla regions at or coronal to the level of the CEJ. Vertical incisions were also sutured. At all times, caution was maintained to avoid overcompression of the test CMX biomaterial. Contralateral control-site surgical procedures were identical to the test sites, with the exception that in the place of CMX, subepithelial CTGs were used.<sup>10</sup>

Patients were prescribed doxycycline post-surgery and instructed to avoid excessive muscle traction or trauma to the treated areas for the first 3 weeks. Chlorhexidine mouthrinses were prescribed for the first 2 weeks. In weeks 2 to 4, patients were instructed to apply chlorhexidine rinse with cotton swabs, after which they used ultrasoft toothbrushes. They were recalled for professional cleanings at weeks 4, 12, and 24.

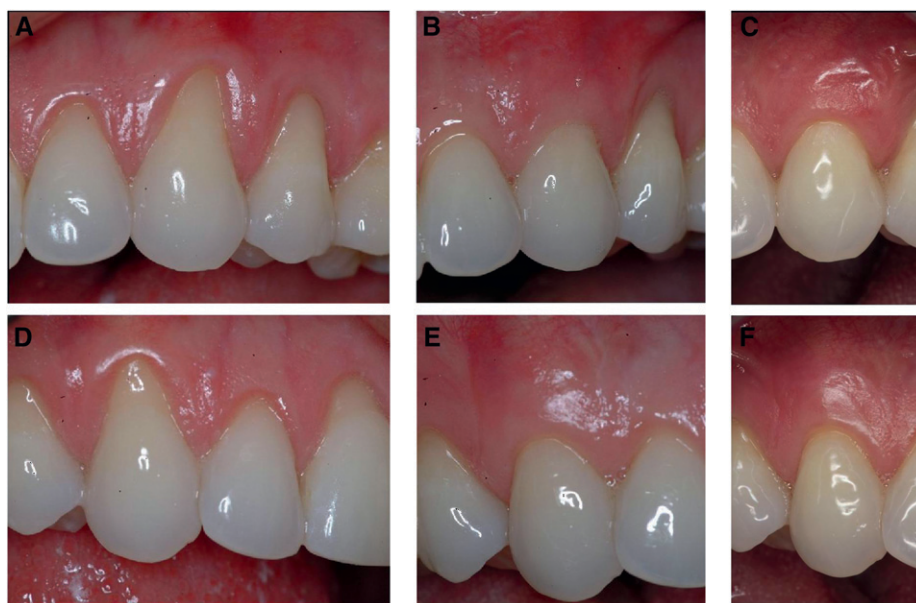
All patients were seen on a 3- to 6-month maintenance interval for the 5 years after their surgery. Five were seen exclusively in the authors' office for maintenance care.



**Figure 1.**

Histologic section (hematoxylin & eosin stain) of gingiva and cross-section (scanning electron micrograph) of CMX.

† Mucograft, Geistlich Pharma, Wolhusen, Switzerland.



**Figure 2.**

Baseline, 6-month, and 5-year results for contralateral control CTG + CAF (A through C) and test CMX + CAF (D through F) sites.

Five or more years after their original treatment, the study patients were recalled for follow-up measurements under a protocol and patient informed-consent process approved by an institutional review board<sup>†</sup> and according to federal (21 CFR 56) and Health Insurance Portability and Accountability Act requirements.

Consistent with the original study, at the 5-year recall the primary efficacy measurement was recession depth and width, recorded as percentage RC. In addition, the following secondary efficacy parameters were measured: 1) width of keratinized tissue (KTW); 2) probing depth (PD); 3) clinical attachment level (CAL); 4) clinician rating of color and texture compared with surrounding tissues; and 5) patient esthetic satisfaction.

The independent, masked, calibrated examiner from the original study (Rebecca Showalter, registered dental hygienist, Perio Health Professionals, Houston, TX) performed all measurements and assigned color and texture binary ratings. Examinations were made in the clinic, not by comparing photographs (although photographs were also obtained). Calibrated 15-mm probes<sup>§</sup> were used, and measurements were rounded up to the nearest half-millimeter. Vertical probing measures were made at the mid-buccal aspect of treated teeth measured from the CEJ to the free gingival margin.

All descriptive and inferential statistical analyses were performed using statistical software.<sup>||</sup> Continuous variables were recorded with the mean, SD, median, minimum, and maximum values. Categorical data were recorded with the frequency and percentage of

patients per treatment group, when applicable. Treatment differences in continuous variables were assessed using paired *t* tests, and treatment differences in categorical variables were assessed using McNemar test. For inferential tests, a *P* value of  $\leq 0.05$  was considered statistically significant. Statistical tests were two-sided.

## RESULTS

Of the original 25 patients, 17 (five males and 12 females, mean age:  $51.3 \pm 13.9$  years) were available for a 5-year recall. Seven of the eight patients unavailable for recall had moved, were not reachable, or had conflicting engagements, and one had received a class 5 restoration that eradicated the baseline measurement reference point. The demographics of the original study sample can

be found in the original publication.<sup>7</sup> Case photo comparisons, including the patients from the original publication, are provided in Figure 2.

Mean RC between 6 months and 5 years changed from 89.5% to 77.6% for CMX + CAF test sites and 97.5% to 95.5% for CTG + CAF control sites (Table 1). The 6-month to 5-year RC changes were not significantly different between therapies ( $P = 0.16$ ) (Table 2). For CMX + CAF, nine sites remained unchanged, seven declined, and one increased. For CTG + CAF, 16 of the 17 sites remained unchanged, and one declined. The best cases, i.e., 100% RC, tended to remain stable, whereas the single site that increased in RC was a CMX + CAF test site that progressed from 66% to 100% coverage. Complete RC (CRC) was 53% (nine of 17 sites) for CMX + CAF and 88% (15 of 17 sites) for CTG + CAF at 5 years, and the change in 6-month to 5-year CRC was not significantly different between the two therapies ( $P = 0.69$ ).

At 5 years, average KTW was  $>3$  mm for both test and control sites (averaging 3.41 and 4.12 mm, respectively), with no (though approaching) statistically significant difference in KTW change between the two therapies over the duration ( $P = 0.11$ ). Mean change in KTW for the test CMX + CAF therapy was approximately  $-0.7$  mm, and mean change for the control CTG + CAF therapy was essentially zero. All sites for both therapies maintained  $\geq 2$  mm KTW at 5 years.

<sup>†</sup> Western Institutional Review Board, Puyallup, WA.

<sup>§</sup> 15 UNC Novatech Color-Coded Probe, Hu-Friedy, Chicago, IL.

<sup>||</sup> SAS, v.9.2 or later, SAS Institute, Cary, NC.

**Table 1.****Average [mean  $\pm$  SD (95% CI)] and Count [n (%)] Measures for Test and Control Therapies at 6 Months and 5 Years (n = 17)**

Clinical Measure	CMX + CAF (test)	CTG + CAF (control)
RC (%)		
6 months	89.5 $\pm$ 19.2 (80.4 to 98.6)	97.5 $\pm$ 10.4 (92.5 to 100)
5 years	77.6 $\pm$ 29.2 (63.7 to 91.4)	95.5 $\pm$ 12.8 (89.4 to 100)
CRC		
6 months	12 (70.6)	16 (94.1)
5 years	9 (52.9)	15 (88.2)
KTw (mm)		
6 months	4.12 $\pm$ 1.17 (3.56 to 4.67)	4.18 $\pm$ 1.22 (3.59 to 4.78)
5 years	3.41 $\pm$ 1.06 (2.91 to 3.92)	4.12 $\pm$ 0.88 (3.70 to 4.53)
PD (mm)		
6 months	1.76 $\pm$ 0.59 (1.46 to 2.07)	1.76 $\pm$ 0.53 (1.49 to 2.04)
5 years	1.65 $\pm$ 0.46 (1.41 to 1.88)	1.50 $\pm$ 0.47 (1.26 to 1.74)
CAL (mm)		
6 months	2.09 $\pm$ 0.85 (1.68 to 2.49)	1.85 $\pm$ 0.81 (1.47 to 2.24)
5 years	2.35 $\pm$ 0.96 (1.89 to 2.81)	1.65 $\pm$ 0.70 (1.31 to 1.98)

CRC = complete root coverage.

**Table 2.****Changes in Outcomes [mean  $\pm$  SD (95% CI) or n (%)] From 6 Months to 5 Years (n = 17)**

Clinical Measure Change	CMX + CAF (test)	CTG + CAF (control)	p*
RC (%)	-11.9 $\pm$ 22.5 (-22.6 to -1.2)	-2.0 $\pm$ 8.1 (-5.8 to 1.9)	0.16
CRC status			0.69
Complete to incomplete	4 (23.5)	1 (5.9)	
No change	12 (70.6)	16 (94.1)	
Incomplete to complete	1 (5.9)	0 (0.0)	
KTw (mm)	-0.71 $\pm$ 1.20 (-1.28 to -0.140)	-0.06 $\pm$ 1.32 (-0.69 to 0.57)	0.11
PD (mm)	-0.12 $\pm$ 0.82 (-0.54 to 0.30)	-0.26 $\pm$ 0.75 (-0.65 to 0.12)	0.59
CAL (mm)	0.26 $\pm$ 0.97 (-0.20 to 0.73)	-0.21 $\pm$ 0.77 (-0.57 to 0.16)	0.02

CRC = complete root coverage.

\* Difference between treatment group continuous variables (change in RC, KTw, PD, and CAL) was calculated using paired Wilcoxon signed-rank test. The categorical variable (change in CRC) was calculated using McNemar test.

PD stayed the same or improved in 13 of 17 sites, both test and control, and the change (on the average less than -0.3 mm for both therapies) over the duration of the study was not significantly different between therapies ( $P=0.59$ ). CAL change from 6 months to 5 years was slightly greater for CTG + CAF (0.26 mm) versus CMX + CAF (-0.21 mm,  $P=0.02$ ).

Tissue color match to surrounding tissues remained similar for both therapies throughout the study, with almost all sites "equally red" compared with surrounding tissue (Table 3). However, there was a difference in tissue texture between therapies at both 6 months and 5 years,

with 15 CMX + CAF sites "equally firm" (the remainder "more firm") and 11 CTG + CAF "more firm" (the remainder "equally firm") at 5 years. Satisfaction remained high, with approximately  $\geq 90\%$  of patients (15 CMX + CAF and 16 CTG + CAF) still satisfied or very satisfied with their outcomes at 5 years. There was no statistical difference in satisfaction at any time point.

## DISCUSSION

The authors set out to investigate CMX as an alternative to palatal graft harvests for RC. Pleased with the results seen at 6 months and 1 year, the authors wanted to

**Table 3.****Six-Month and 5-Year Color and Texture Outcomes [n (%)] (n = 17)**

Esthetics and Patient Satisfaction	CMX + CAF (test)	CTG + CAF (control)	P*
Color match to surrounding tissue			
6 months			>0.99
Less red	0 (0.0)	0 (0.0)	
Equally red	11 (64.7)	12 (70.6)	
More red	6 (35.3)	5 (29.4)	
5 years			0.63
Less red	0 (0.0)	2 (11.8)	
Equally red	15 (88.2)	14 (82.4)	
More red	2 (11.8)	1 (5.9)	
Texture match to surrounding tissue			
6 months			0.006
Less firm	6 (35.3)	0 (0.0)	
Equally firm	10 (58.8)	9 (52.9)	
More firm	1 (5.9)	8 (47.1)	
5 years			0.02
Less firm	0 (0.0)	0 (0.0)	
Equally firm	15 (88.2)	6 (35.3)	
More firm	2 (11.8)	11 (64.7)	
Patient satisfaction			
6 months			0.13
Very satisfied	13 (76.5)	11 (64.7)	
Satisfied	3 (17.6)	3 (17.6)	
Neutral	0 (0.0)	1 (5.9)	
Unsatisfied	1 (5.9)	1 (5.9)	
Very unsatisfied	0 (0.0)	1 (5.9)	
5 years			>0.99
Very satisfied	9 (52.9)	10 (58.8)	
Satisfied	6 (35.3)	6 (35.3)	
Neutral	0 (0.0)	0 (0.0)	
Unsatisfied	2 (11.8)	1 (5.9)	
Very unsatisfied	0 (0.0)	0 (0.0)	

\* Difference between treatment groups calculated using paired Wilcoxon signed-rank test.

confirm that acceptable results could be maintained long term. At  $\geq 5$  years after therapy, average RC was 77.6%, and CRC occurred in nine of 17 sites (53%). In addition, the average KTw was maintained at  $>3$  mm. These parameters (RC, CRC, and KTw) showed no significant difference in change between test and control therapies over the 5-year evaluation. As is expected for the CTG + CAF gold standard, CMX + CAF results were found to be acceptable at  $\geq 5$  years.

But what are “acceptable” results? Certainly, clinicians look for good RC, a stable cuff of keratinized tissue, good esthetics, and an outcome that patients appreciate. The literature helps define what might be “good” root coverage. Short-term (6-month to 1-year) systematic reviews can be helpful. In Chambrone et al.’s meta-analysis of procedures used in Miller Class I and II randomized controlled trials ( $\geq 6$  months in duration and  $>10$  patients), CTG + CAF yielded mean RC values from 64.5% to 97.3% and averaged 85%, and CRC results

were 10% to 96.1% and averaged 54%.<sup>3</sup> Technique, patient selection, and (therefore) results varied to produce such ranges, but the CMX + CTG results at 6 months for RC (89.5%) and CRC (70.5%) compare favorably. Indeed, as Buti et al.<sup>4</sup> found in their Bayesian network meta-analysis of RC procedures, “the surgical procedures with the highest probability [Pr] of being the best treatments were the combined CAF + CTG treatment (Pr = 40%) and CAF + [CMX] treatment (Pr = 25%).” Likewise, CMX + CAF was ranked most highly, along with CTG + CAF, for KTw gains.<sup>4</sup> In the present study, KTw changes over 5 years between CTG + CAF and CMX + CAF were not significantly different, with an overall, average difference between therapies of 0.21 mm. All sites maintained  $\geq 2$  mm KTw, considered by some to be the suitable KTw for good maintenance prognosis,<sup>11</sup> and the average KTw for CMX + CAF therapy was 3.4 mm (again, what would be considered acceptable).

Esthetics also appeared to be acceptable. Color match to surrounding tissues was not significantly different between the two therapies at any time point, whereas CMX + CAF texture provided a significantly better match to surrounding tissues compared with CTG + CAF, with an increasing tendency for matching over 5 years. Most importantly, patients were almost completely and equally satisfied with both therapies.

The remaining question is how gold standard CTG + CAF compares with CMX + CAF and other graft harvest alternatives long term. Within the Chambrone et al. meta-analysis, only one study followed CTG + CAF results out to 5 years.<sup>3,12</sup> It yielded 85% RC and 49% CRC. Again, the evaluation of CMX + CAF at 5 years compares favorably with 78% RC and 53% CRC. In the evaluation of human platelet-derived growth factor (PDGF) and enamel matrix derivative (EMD), long-term RC was 74% and 83%, respectively, and CRC was 60% and 56%.<sup>5,6</sup> In Pini-Prato et al., long-term (5-year) results for CAF alone were somewhat lower, at  $\approx$ 72% RC and 35% CRC, compared with CTG + CAF results of 89% RC and 52% CRC.<sup>13</sup> Harris evaluated acellular dermal matrix (ADM) + CAF versus CTG + CAF at  $\geq$ 3 years and found a statistically significant loss in recession coverage for ADM but not CTG.<sup>14</sup> At  $\geq$ 3 years, CTG + CAF yielded 97% RC and 90% CRC, whereas ADM + CAF yielded 66% RC and 40% CRC.<sup>14</sup> Table 4 provides an overview comparison of these long-term outcomes. (Readers may also wish to refer to the 2015 American Academy of Periodontology Regeneration Workshop systematic review and consensus report.<sup>15,16</sup>)

As reassuring as the statistical evaluation of the test and control therapies reported herein might be, clinical significance is also important. Dental professionals do not treat numbers; we treat patients. CTG + CAF root coverage and keratinized tissue measures were, on average, higher than those of the test therapy; however, by using CMX + CAF, the authors were able to effec-

tively treat patients without harvesting tissue from the palate, an alternative patients have told us they prefer,<sup>17</sup> resulting in a harvest graft alternative much like the alternatives preferred in other fields of medicine. For example, in orthopedics, even though autogenous bone grafts are the gold standard, substitute grafts are routinely used to avoid harvest site morbidity and provide sufficient graft volumes. Likewise, in vascular surgery, though autogenous (saphenous) veins provide better long-term patency, lower-morbidity and easier-to-use synthetic grafts are used routinely, because they perform satisfactorily, are available in unlimited supply, and shorten surgery time.

The authors would like to see more long-term confirmatory CMX + CAF studies, and also longer-term studies, perhaps out to 10 years. Similar (though not paired, within-patient defect) comparisons of CMX + CAF versus CTG + CAF in Miller Class I and II recessions have been performed by Cardaropoli et al.<sup>18</sup> (18 patients with 22 recession defects) and Aroca et al. (22 patients with 156 defects),<sup>19</sup> who used a modified tunneling technique. RC was slightly lower for CFX + CAF compared with CTG + CAF (94% versus 97%<sup>18</sup> and 71% versus 90%<sup>19</sup>) but with no need for a harvest graft and, in Aroca's study, reduced surgical time. However, those studies had a 12-month follow-up, and longer-term confirmatory studies are still needed to test for statistical differences and, more importantly, clinical differences that the present study might not have detected given its limited sample size. Clearly, differing techniques among investigators provide different results, and for this reason the authors urge readers to be cautious when interpreting the results. Likewise, the study model involves contralateral, single-tooth treatments, and although CMX + CAF has been shown to be superior to CAF alone in multiple-tooth recession defects,<sup>20</sup> the authors suggest that multiple-tooth studies comparing CMX + CAF to CTG + CAF should also be followed long-term.

**Table 4.**

**Long-Term RC Results for CTG + CAF Therapy and Harvest Graft Alternative Therapies; Range of Results May Also Reflect Patient, Site, and Technique Variability**

Treatment	Long-Term Results		Study
	RC (%)	CRC (%)	
EMD + CAF (10 years)	83	56	McGuire and Scheyer 2010 <sup>7</sup>
CMX + CAF (5 years)	78	53	This study
PDGF + CAF (5 years)	74	60	McGuire et al. 2014 <sup>5</sup>
CAF alone (5 years)	72	35	Pini-Prato et al. 2010 <sup>13</sup>
ADM + CAF (3 years)	66	40	Harris 2004 <sup>14</sup>
CTG + CAF	89 to 97	52 to 90	All of the above

## CONCLUSIONS

As stated in the authors' original 2010 publication,<sup>7</sup> "Overall patient-reported esthetic satisfaction with both test and control treatments was equivalent. When balanced with patient-reported outcomes for esthetics and compared with historical root coverage reported by other investigators, CMX + CAF seems to present a viable alternative to the traditional CTG + CAF gold standard, without the morbidity of graft harvest." Given the outcomes reported herein, it would appear that acceptable CMX + CAF recession coverage, and coverage clinically comparable to traditional CTG + CAF therapy, can be maintained over the long term.

## ACKNOWLEDGMENTS

This study was supported, in part, by an educational grant provided by Geistlich Pharma AG, Wolhusen, Switzerland. Drs. McGuire and Scheyer received lecture and associated travel reimbursement from Geistlich Pharma. The authors thank Rebecca Showalter, registered dental hygienist, Director of Clinical Research, Perio Health Clinical Research Center, Houston, Texas (PHCRC), for recording outcome measures and coordinating data, and Cindy Wainscott, CDA, PHCRC, for study administration.

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Submitted June 26, 2015; accepted for publication September 17, 2015.