Randomized, Controlled Clinical Trial to Evaluate a Xenogeneic Collagen Matrix as an Alternative to Free Gingival Grafting for Oral Soft Tissue Augmentation

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Background: The standard of care for increasing keratinized tissue (KT) and vestibular area is an autogenous free gingival graft (FGG) and vestibuloplasty; however, there is morbidity associated with the harvest of autogenous tissue, and supply is limited. The purpose of this study is to determine if a xenogeneic collagen matrix (CM) might be as effective as FGG.

Methods: This study is a single-masked, randomized, controlled, split-mouth study of 30 patients with insufficient zones of KT (<2 mm). It uses a within-patient treatment-comparison design to establish non-inferiority of the test (CM) versus control (FGG) therapy. The primary efficacy endpoint was change in KT width (ΔKT) from surgery to 6 months post-surgery. Secondary endpoints included traditional periodontal measures, such as clinical attachment level, recession, and bleeding on probing. Patient-reported pain, discomfort, and esthetic satisfaction were also recorded. Biopsies were obtained at 6 months.

Results: Surgery and postoperative sequelae were uneventful, with normal healing observed at both test and control sites. The primary outcome, ΔKT width at 6 months, did not establish non-inferiority of CM compared to FGG ($P = 0.9992$), with the FGG sites averaging 1.5 mm more KT width than CM sites. However, the amount of new KT generated for both therapies averaged ≥2 mm. Secondary outcomes were not significantly different between test and control sites. All site biopsies appeared as normal mucoperiosteum with keratinized epithelium. CM sites achieved better texture and color matches, and more than two-thirds of patients preferred the appearance of their CM sites.

Conclusion: With the proviso of sufficient KT (≈2 mm in width) and study goals of lower morbidity, unlimited supply, and patient satisfaction, CM appears to be a suitable substitute for FGG in vestibuloplasty procedures designed to increase KT around teeth. *J Periodontol 2014;85:1333-1341.*

KEY WORDS

Collagen; gingiva; keratin; transplantation, autologous; transplantation, heterologous.

Oral soft tissue augmentation procedures are performed routinely in the United States in an attempt to maintain gingival health in patients. Since the late 1960s, clinicians have routinely corrected insufficient keratinized tissue (KT) and insufficient vestibules by placing autogenous free gingival grafts (FGGs) and surgically releasing the vestibular area, i.e., vestibuloplasty.[1-13] Facial mucosa is removed to create a wound bed, and soft tissue incisions are extended to create suitable vestibules. The standard of care is an FGG harvested from the palate and sutured to the wound bed. Initially, the FGG is supported by plasmatic circulation, and then it is revascularized from the surrounding bed. The procedure tends to be judged in terms of its ability to generate a band of KT of ≥2 mm in width, representing ≥1 mm of attached gingiva, and its success verges on 100%.

However, there is morbidity associated with soft tissue harvest from the palate, and the palate provides limited donor tissue, allowing only a few teeth to be treated at one time.[14,15] Some patients present with difficult-to-control bleeding at the graft harvest site; if a patient has multiple sites that need to be treated, multiple surgeries or a single,

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limited treatment of only the teeth with the poorest prognoses is performed. FGGs may also produce an undesirable esthetic result, colloquially referred to as a "tire patch," which is off-color and texturally distinct from surrounding tissues.

Within the dental community, there is a strong desire to identify an alternative graft material that could be used as a substitute for FGGs. A suitable substitute would reduce morbidity, patient pain, and the number of surgical sites required and increase the number of teeth that could be treated in one surgical visit.

Recently, a new xenogeneic collagen matrix (CM) with two structures has proved promising as a graft substitute in soft tissue augmentation procedures.[16-19] For patients with insufficient KT (<2 mm), the authors decided to test how CM might compare with FGG in terms of KT width generation.

MATERIALS AND METHODS

Study Design

The authors designed and implemented a single-masked (examiner: Rebecca Showalter, Perio Health Professionals, Houston, TX), randomized, controlled, split-mouth study of 30 patients with insufficient zones of KT (<2 mm). The study uses a within-patient treatment comparison designed to establish non-inferiority. The study sample was derived from the population of patients who presented at the authors' private practice from November 3, 2010 to March 16, 2011 and met predetermined selection criteria.

To assess the safety and effectiveness of CM compared to FGG, traditional clinical measures of periodontal health and healing were recorded. Measurements included: 1) plaque score; 2) bleeding upon probing; 3) recession depth; 4) width of keratinized tissue; 5) probing pocket depth; 6) vestibular depth; 7) clinical attachment level; 8) resistance to muscle pull; and 9) inflammation score. The time required to perform the CM and FGG surgeries was also recorded and esthetics and patient preference were compared.

The protocol and patient informed consent process were approved by an institutional review board (Western IRB) and complied with federal (21 CFR 56) and Health Insurance Portability and Accountability Act requirements.

Patients who agreed to participate in the trial (six males and 24 females, aged 28.1 to 70.6 years; mean age: 51.9 years) were screened for eligibility according to age (18 to 70 years) and possession of contralateral teeth with <2 mm of KT in the same jaws. No females of childbearing age or patients with systemic healing conditions or history of tobacco use were enrolled. Additional criteria and details of inclusion and exclusion criteria can be found in supplementary Table 1 in the online *Journal of Periodontology*. All patients provided written informed consent to participate.

Before baseline surgery, demographics and medical and dental histories were collected. An oral exam and dental cleaning were performed, clinical measurements obtained, photographs taken, oral hygiene procedures reviewed, periapical radiographs obtained, and a pregnancy test performed on women of childbearing potential. If indicated, patients were fitted with bite guards.

Eligible patients had at least two study teeth identified and randomized to treatment with CM or FGG. Up to four adjacent teeth were treated per quadrant; however, only one tooth in each quadrant, selected for the best match tooth in arch position and amount of recession to the contralateral tooth, was identified as a test tooth. Alveolar bone level, surgical position margin, and graft base measurements were obtained at baseline. Photos were taken before, during, and after the procedures, and patients were prescribed antibiotics and provided with a 0.12% chlorhexidine mouth rinse and oral hygiene instructions postoperatively.

The first follow-up office visit occurred 1 week post-surgery. Any changes in medications or adverse events were documented, and photos of the test and control sites were taken along with clinical measurements. Oral hygiene instructions were reviewed.

Further follow-up evaluations occurred at 1, 3, and 6 months post-surgery. Any changes in medications or adverse events were documented, and photos of the test and control sites, along with clinical measurements, were obtained. Dental cleanings were also performed. At the latter time points (week 4 and month 3), texture and color of the surgical sites were evaluated. An oral exam was performed at 1 and 6 months. At 6 months post-surgery, a patient questionnaire regarding esthetics and treatment preference was administered, radiographs were obtained, and a pregnancy test was given to females of childbearing potential. Biopsies were taken of six sites (three CM and three FGG) at 6 months.

Parameters

Primary measure. The primary measure was change in KT width (ΔKT) from time of surgery to 6 months post-surgery.

Secondary measures. Secondary measures included: 1) change in clinical attachment level (ΔCAL), change in probing depth (ΔPD), change in recession depth (ΔREC), bleeding following angulated probing (BOP), resistance to muscle pull, and inflammation during 6 months; 2) time required to perform surgery for test (CM) and control (FGG) treatments; 3) esthetics (texture and color match compared to

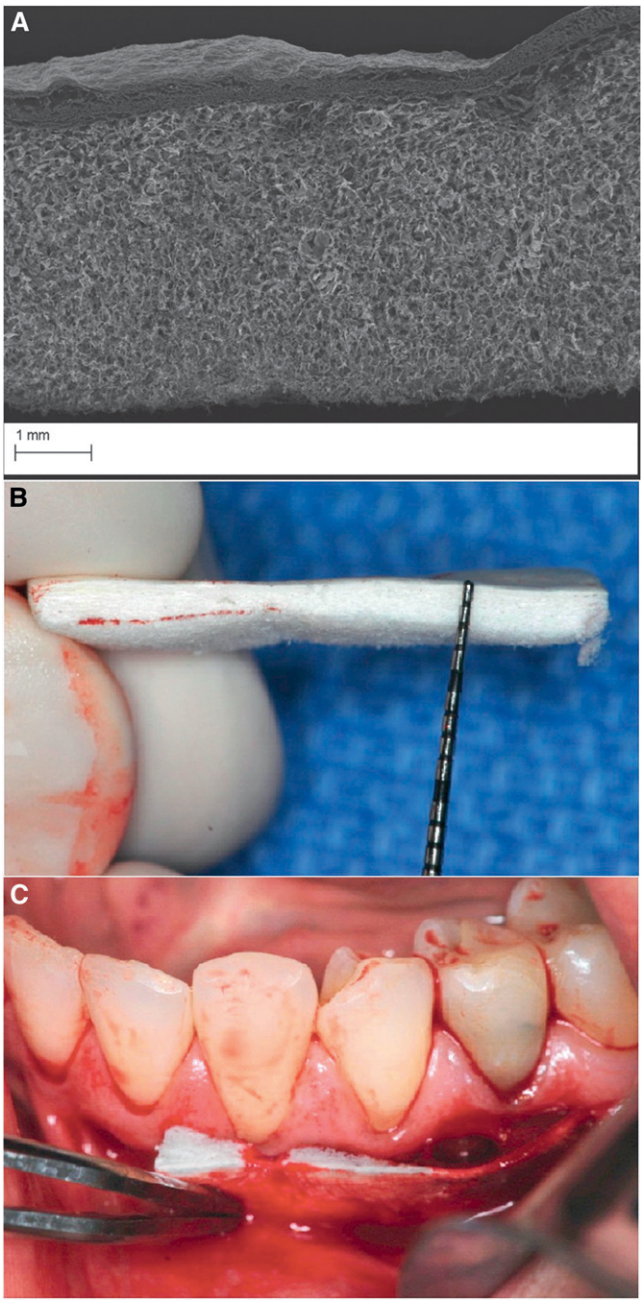

Figure 1.
A) *Cross-sectional scanning electron microscopy of the CM. The top layer is the compact layer; the bottom shows the thicker, more porous layer.* ***B)*** *Clinical view of CM, displaying its thickness.* ***C)*** *Intraoperative CM view freshly placed into the recipient bed.*

surrounding tissue) during 6 months; and 4) patient-reported pain.

Post hoc measure. The post hoc measure was ΔKT 3 months following treatment.

Calibrated probes† 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 cemento-enamel junction to the free gingival margin. Schiller iodine was used to demarcate keratinized and non-keratinized tissues. All measures were recorded at baseline except treatment-dependent measures of color and texture. After surgery, no subgingival instrumentation or probing was performed for 3 months.

A masked, calibrated examiner (Rebecca Showalter, Perio Health Professionals, Houston, TX, calibrated to a "gold standard examiner" with no intra- or interexaminer variation >1) performed all measurements and assigned color and texture binary ratings of "equal or not equal to surrounding native tissue" at 1, 3, and 6 months. Examinations were performed in the clinic, not by comparing photographs. Photographs of treatment sites were taken at baseline, surgery, and all follow-up time points.

Sample Size, Identification, and Selection

Sample size was predicated on obtaining 80% power for testing the primary study endpoint, which evaluated whether CM was not inferior to FGG in the generation of KT from baseline to 6 months. This assumed a paired *t* test of non-inferiority with a non-inferiority margin of 1.0 mm, a within-patient standard deviation of 1.0 mm, and a one-sided α of 0.05. Under these assumptions, a sample size of 27 was required to power the primary endpoint. To account for potential loss to follow-up, 30 patients were enrolled in the trial.

Study Test Material

The CM test material‡ is a U.S. Food and Drug Administration 510(K)–cleared device composed of pure, porcine collagen obtained by standardized, controlled manufacturing processes. The collagen was extracted from veterinary-certified pigs and purified to avoid antigenic reactions. The matrix was made of collagen type I and type III without further cross-linking. CM was sterilized in double blisters by γ-irradiation.

CM has two structures (Fig. 1): 1) a compact structure, facing the oral cavity, consisting of a denser collagen that protects the wound but allows tissue adherence for favorable wound healing; this layer has a smooth texture with appropriate properties to accommodate suturing to the host mucosal margins; and 2) a thicker, porous collagen that encourages tissue integration; this porous surface is placed adjacent to the host tissue to facilitate organization of the blood clot and promote neo-angiogenesis.

Surgical Procedure

Patients were randomized at baseline, with test or control treatment assigned to right or left sides. To ensure that there was no bias in assigning treatment, a predetermined computer-generated

† UNC-15, Novatech Color-Coded Probe, Hu-Friedy, Chicago, IL.
‡ Mucograft, Geistlich Pharma, Wolhusen, Switzerland.

Table 1.

Demographics of Study Patients

Patients (n)	30
Age (years)	
Mean ± SD	51.9 ± 11.2
Median	54.8
Range	28.1 to 70.6
Sex (n [%])	
Males	6 (20.0)
Females	24 (80.0)
Ethnicity (n [%])	
Latino or Hispanic	1 (3.3)
Not Latino or Hispanic	29 (96.7)
Race (n [%])	
White	26 (86.7)
Black or African American	1 (3.3)
Native Hawaiian or other Pacific Islander	0 (0.0)
Asian	1 (3.3)
American Indian or Alaska Native	0 (0.0)
Other	2 (6.7)

randomization scheme was contained in sealed envelopes, including randomizations for three factors: 1) treatment side (CM left or right); 2) first treatment (CM or control); and (3) palatal graft side (CM or control). Each of these factors was randomized in a straight 1:1 ratio without blocking, using software[§] with specified seeds for each randomized factor.

After local anesthesia, a partial-thickness dissection was accomplished to remove the mucosa and any marginal KT from the facial aspect of the test and control sites. As first described by Bjorn,[1] a coronal incision was made at the height of the existing mucosa and extending at least to the line angle of the adjacent teeth. Wound beds were only slightly larger than the CM and FGG grafts. CM was sized as widely as possible (apical-coronally) to compensate for its shrinkage, whereas the width of the FGG grafts was ≈4 mm. Vertical incisions were made on both the mesial and distal aspects of the CM sites, extending apically as far as the vestibules allowed. The mesial and distal incisions were then connected apically. Any muscle fibers were removed with scissors, creating a clean periosteal bed. If feasible, a full-thickness horizontal incision was also made just apical to the planned level of FGG or CM placement, separating the periosteum, ensuring that there was no muscle tension on the bed.

CM was cut to fit the wound bed, and care was taken not to crush or compress its matrix structure. It was placed dry (not prewet), and blood was allowed to soak into the matrix to form an initial, stable clot. The randomly assigned palate donor-site FGG was harvested according to standard practices. The CM and FGG test and control materials were placed in direct contact with the appropriate, randomly assigned wound bed and sutured in place with resorbable 5-0 gut sutures into the papillary region on the mesial and distal aspects of the tooth, per traditional FGG procedures.

The lip or cheek adjacent to the graft was placed under tension to make certain that the grafts were free of movement during muscle traction. The FGG and CM sites were left uncovered, i.e., no wound dressing, whereas the graft harvest site was covered with surgical dressing.[‖] Surgery times were recorded for both CM and control FGG treatments, from the time that the surgeon began graft bed preparation until the last suture was tied off.

Post-surgical Care

Patients were instructed to use chlorhexidine (0.12%) mouth rinse for 30 seconds twice daily and to avoid aggressive rinsing while the dressing was in place and excessive muscle tractioning or trauma to the treated areas for the first 4 weeks. Patients were also instructed not to brush the grafted area for the first 2 weeks and to avoid disruptive (crunchy or sharp) foods for the first month following surgery. After 2 weeks, patients were instructed in a brushing technique creating minimal apically directed trauma to the soft tissue of the treated teeth. At 4 weeks, patients resumed normal toothbrushing.

Data Analyses

The primary hypothesis of the study evaluates whether CM was not inferior to control in the generation of KT width from baseline to 6 months. A paired *t* test was used to test for non-inferiority, using a one-sided significance level of 0.05 and a non-inferiority margin of 1.0 mm.

For continuous or quasi-continuous variables, the summary statistics recorded and calculated were N available, mean, standard deviation, median, 95% confidence interval (CI), and range. To account for the split-mouth design of the study, paired Wilcoxon signed-rank tests were used to test for unadjusted treatment differences at individual time points and for unadjusted treatment differences of change across time points. CIs were computed assuming independence of treatment outcomes.

For categoric variables, all categories were summarized with counts and percentages. To account for

§ SAS (PROC PLAN), v.9.2, SAS Institute, Cary, NC.
‖ Coe-Pak, GC America, Alsip, IL.

Table 2.

Baseline Measures (mean ± SD or n [%])

Baseline Parameter	Measure	95% CI	*P*
Clinical			
KT width (mm)			0.3944
Test	0.88 ± 0.61	0.66 to 1.11	
Control	0.77 ± 0.68	0.51 to 1.02	
PD (mm)			0.0766
Test	1.30 ± 0.43	1.14 to 1.46	
Control	1.47 ± 0.47	1.29 to 1.64	
REC (mm)			0.7687
Test	2.55 ± 1.22	2.09 to 3.01	
Control	2.50 ± 1.24	2.04 to 2.96	
CAL (mm)			0.3781
Test	3.75 ± 1.30	3.27 to 4.23	
Control	3.92 ± 1.38	3.40 to 4.43	
BOP			1.0000*
Test	8 (27)		
Control	7 (23)		
Resistance to muscle pull			0.3750*
Test	5 (17)		
Control	8 (27)		
Surgical			
Alveolar bone level (mm)			0.5788
Test	6.18 ± 2.55	5.23 to 7.14	
Control	6.35 ± 2.48	5.42 to 7.28	
Surgical position margin (mm)			0.0005
Test	1.85 ± 1.29	1.37 to 2.33	
Control	2.62 ± 1.32	2.12 to 3.11	
Reference point to graft base (mm)			<0.0001
Test	11.78 ± 2.88	10.71 to 12.86	
Control	6.65 ± 1.22	6.19 to 7.11	
Procedure time (minutes)			0.3774
Test	11.13 ± 3.66	9.76 to 12.50	
Control	10.73 ± 3.85	9.30 to 12.17	

P values testing differences between treatment groups were calculated using paired Wilcoxon signed-rank tests, unless noted otherwise.
* *P* values testing differences between treatment groups were calculated using McNemar tests.

the split-mouth design of the study, McNemar's test was used to test for unadjusted treatment differences at individual time points and for unadjusted treatment differences of change across time points.

Statistical software¶ was used, and with the exception of the primary endpoint, statistical tests were two-tailed, with *P* values <0.05 considered statistically significant.

Histologic Analyses

At 6 months, six 2 × 2–mm punch biopsies down to bone level were removed over the grafted areas in three patients (test and control). Specimens were stored in 4% paraformaldehyde and sent to the histology laboratory at Loma Linda University, Department of Oral Maxillofacial Surgery, Loma Linda, California, for analysis. Samples were embedded for 4 to 5 hours in an embedding gel# and then placed into a mega-cassette and embedded in celloidin-paraffin. Using a microtome, 5-μm sections were cut and stained with hematoxylin and eosin.

RESULTS

Demographics are provided in Table 1. Test and control baseline measurements were comparable (Table 2), with no significant differences, except that baseline wound beds and corresponding graft measures, as specified by study protocol, were larger for CM. Procedure time was not significantly different between the two therapies.

Surgery and postoperative sequelae were uneventful, with normal healing observed at both test

¶ SAS, SAS Institute.
# HistoGel, Richard-Allan Scientific, Kalamazoo, MI.

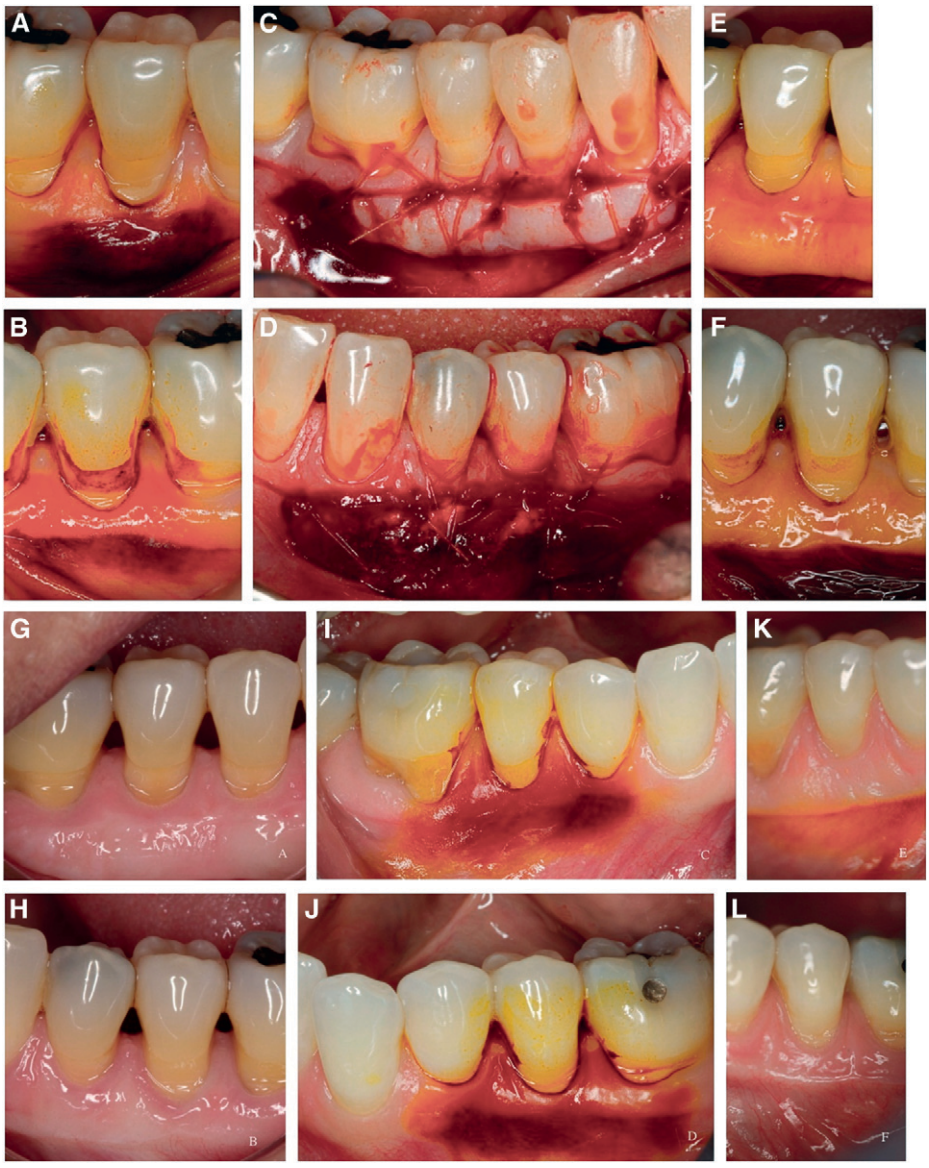

Figure 2.
A *and* ***B)*** *Pretreatment of control and test, respectively, both stained with Schiller iodine to better delineate the mucogingival junction, with no attached gingiva.* ***C*** *and* ***D)*** *Control FGG and test CM in place.* ***E*** *and* ***F)*** *Control and test 6-month follow-up; both stained showing increased KT and attached gingiva.* ***G*** *and* ***H)*** *Baseline control and test, respectively.* ***I*** *and* ***J)*** *Six-month control and test, respectively, stained with Schiller iodine and displaying healthy KT/attached gingiva.* ***K*** *and* ***L)*** *Six-month follow-up of control and test (CM), with test site showing a functional zone of attached and keratinized gingiva.*

CM and control FGG sites (Fig. 2). No unanticipated adverse events were recorded.

The primary outcome of non-inferiority for ΔKT width at 6 months did not establish non-inferiority of CM compared to FGG ($P = 0.9992$; paired t test with 1.0-mm non-inferiority margin). Post hoc analyses of ΔKT width at 3 and 6 months showed significant differences between test and control, with the FGG sites averaging 1.5 mm more KT width than CM sites. The amount of new KT generated for both therapies averaged >2 mm (Table 3). Of the 30 CM cases, 29 achieved ≥2.0 mm KT by 6 months, with a mean of 2.9 mm. All site biopsies appeared as normal mucoperiosteum with keratinized epithelium.

Secondary outcomes were not significantly different between the two modalities, except that average inflammation for CM test sites was higher than FGG test sites at 4 weeks, settling back to not significantly different at later time points. There was no discernible difference in muscle pull resistance between treatments. CM sites achieved better texture and color matches (Table 3). More than two-thirds of patients preferred the appearance of their CM sites (test, n = 21 [70%]; control, n = 9 [30%]).

DISCUSSION

In this examination of CM as a substitute for traditional autogenous graft therapy, the control FGG generated significantly more KT than did the test CM at 6 months (4.4 versus 2.9 mm). However, 29 of 30 CM cases achieved ≥2.0 mm KT at 6 months. It is generally accepted that 2.0 mm KT is desirable,[3,4] but it is unknown whether more KT is necessarily better, a question for which the answer may never be known.

Biopsies, represented by three of the 30 patients, revealed a multilayered, keratinized, squamous epithelium at test and control sites, as also elucidated in a recent study by Schmitt et al.[19] (Fig. 3).

Many substitute graft materials have been used during the years, but when considering the weight of the literature, none have been found to perform as well as FGG for KT gain. In 2009, Thoma et al. provided an extensive review of soft tissue augmentation techniques.[20] The treatments examined included: 1) no treatment or scaling and root planing (SRP) alone; 2) apically positioned flap/vestibuloplasty (APF/V); 3) APF/V plus autogenous tissue (FGG or connective tissue graft [CTG]); 4) APF/V plus allogenic tissue, such as acellular dermal

Table 3.

Primary and Secondary Outcomes (mean ± SD or n [%])

Parameter	Outcome	95% CI	*P*
Primary			
KT width (mm)			
Three months			<0.0001
Test	2.75 ± 0.74	2.47 to 3.03	
Control	4.07 ± 0.70	3.80 to 4.33	
Six months			<0.0001
Test	2.92 ± 0.88	2.59 to 3.25	
Control	4.42 ± 0.64	4.18 to 4.66	
Secondary			
Change in PD (mm)			0.7301
Test	0.08 ± 0.49	–0.10 to 0.27	
Control	0.05 ± 0.55	–0.15 to 0.25	
Change in REC (mm)			0.3256
Test	–0.13 ± 0.52	–0.33 to 0.06	
Control	–0.22 ± 0.49	–0.40 to –0.04	
Change in CAL (mm)			0.1608
Test	0.05 ± 0.70	–0.21 to 0.31	
Control	–0.12 ± 0.61	–0.34 to 0.11	
BOP			0.1250*
Test	7 (23)		
Control	3 (10)		
Resistance to muscle pull			NA (equivalent)
Test	30 (100)		
Control	30 (100)		
Texture match to surrounding tissue			<0.0001*
Test	29 (97)		
Control	0 (0)		
Color match to surrounding tissue			<0.0001*
Test	26 (87)		
Control	3 (10)		

P values testing differences between treatment groups were calculated using paired Wilcoxon signed-rank tests, unless noted otherwise. NA = not applicable.
* *P* values testing differences between treatment groups were calculated using McNemar tests.

matrix (ADM); and 5) APF/V plus tissue- engineered (TE) live-cell therapies, such as expanded, allogenic gingival fibroblasts or allogenic keratinocyte/fibroblast bilayered constructs (BCTs). Compared to no treatment or SRP alone, APF/V plus autogenous tissue resulted in a significant weighted mean difference of ≈4.5 mm KT. Mean gains in KT were significantly greater combining APF/V with autogenous grafts versus using APF/V alone. However, APF/V plus allogenic grafts, including ADM, were only slightly more favorable than APF/V alone, a borderline statistical difference. There was significantly more graft shrinkage (loss of graft area compared to baseline with time) for allogenic grafts. For example, Wei et al. showed ADM to be less effective at generating attached tissue, compared to FGG, because of shrinkage and "inconsistent quality" of ADM-generated attached tissue (for ADM versus FGG, the study reported ≈3.2 versus 6.2 mm of attached tissue, with 71% versus 16% shrinkage).[21]

For TE constructs, McGuire and Nunn found ≈1 mm more KT generated for control APF/V plus FGG compared to a human fibroblast–derived dermal substitute (overall, ≈3.9 versus 2.7 mm of KT width).[22] Mohammadi et al. found periosteal fenestration alone generated ≈4.1 mm KT, whereas cultured gingival fibroblasts generated a mean KT of ≈3.2 mm.[23] In their multicenter, pivotal trial examining BCT, McGuire et al. found ≈4.6 mm KT generated by APF/V plus FGG, versus 3.2 mm for APF/V plus BCT.[24]

Today, it would generally appear that APF/V plus FGG is the gold standard therapy and can be expected to generate ≥4 mm KT, whereas graft substitutes, including TE constructs, appear to generate ≈3 mm KT. However, surgical technique, particularly wound bed preparation and the size of the substitute

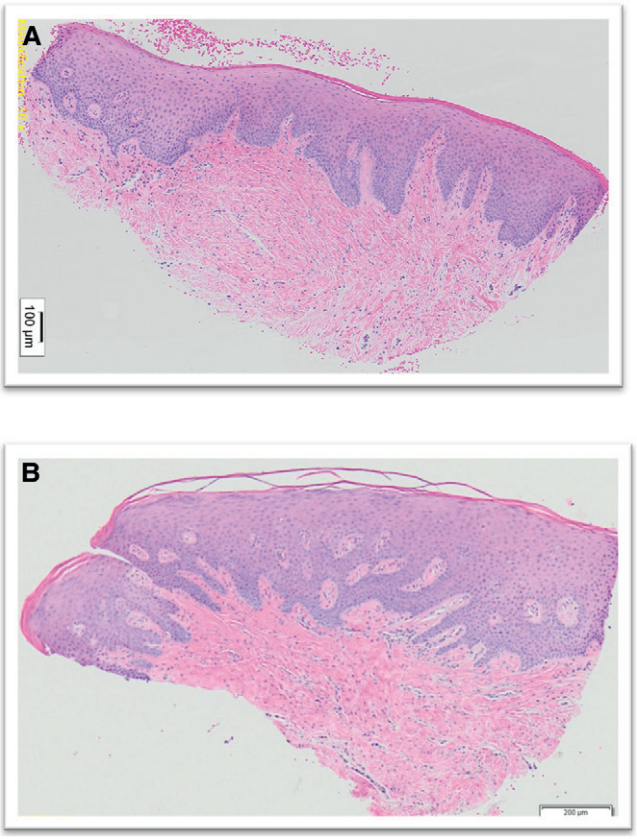

Figure 3.
*Histologic findings of **A)** control (original magnification × 10) and **B)** test (original magnification × 40). All biopsies appeared as normal mucoperiosteum, with keratinized epithelium.*

graft (and its corresponding shrinkage), greatly influence KT results.

In the authors' experience, CM has been easy to use and has had the significant advantage of healing well in both exposed and submerged environments. Anticipating the KT shrinkage observed with CM by creating larger wound beds is advisable. Also, according the manufacturer, crushing the biomaterial, which could compromise its open matrix structure and the ability of healing cells to enter, should be avoided. The authors are unaware of any other substitute grafting materials that are indicated for or function and heal as well in both exposed and covered healing situations.

Patients were generally pleased with CM results. CM sites achieved better texture and color matches, and more than two-thirds of the patients preferred the appearance of CM therapy. But patient expectations and preferences are surprisingly difficult to accurately capture. Because of the growing importance of patient-reported outcomes (PROs), the authors spent an inordinate amount of time and resources in developing appropriate instruments for collecting valid PRO endpoints. The results of these efforts and lessons the authors learned about incorporating PROs in periodontal clinical trials can be found in the commentary that accompanies this article.[25]

The reasons for exploring autogenous graft substitutes are potential ease of use and unlimited supply, coupled with patient preference. Most of the authors' mucogingival augmentation patients present at the office not only unaware there is a problem but also unaware of how much KT width they ought to have. They are simply interested in doing what needs to be done to maintain health, and they would like to resolve their issues with the fewest number of visits, the least discomfort, and the best esthetic result. Given these patient goals, composite scores that take into account not only traditional clinical measures such as KT width but also outcomes such as treatment preference and esthetics may be more appropriate and may better help periodontists present benefits, risks, and treatment options to patients.

Further studies are indicated to better understand the performance of CM. In this study, the amount of KT increased for both CM and FGG sites from 3 to 6 months. The authors question whether CM is capable of creeping attachment, and they also want to examine the long-term stability of CM tissue augmentation therapy. These questions will need to be answered.

CONCLUSION

With the proviso of sufficient KT (≈2 mm in width) and study goals of lower morbidity, unlimited supply, and patient satisfaction, CM appears to be a suitable substitute for FGG in vestibuloplasty procedures designed to increase KT around teeth.

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