



Analysis of the treatment of RT2 recessions with a xenogeneic collagen matrix vs. connective tissue graft combined with a coronally advanced flap. A double-blinded randomized clinical trial

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Abstract

Objectives To compare the clinical efficacy in terms of mean root coverage in RT2 recession treated with a coronally advanced flap combined with a xenogeneic collagen matrix versus a connective tissue graft.

Materials and methods A total of 20 patients were randomized to receive one of two treatments: coronally advanced flap + xenogeneic collagen matrix (test group) and coronally advanced flap + connective tissue graft (control group). Patient-related outcomes measures and professional aesthetic assessment by root esthetic score were performed. A descriptive and analytical statistical analysis of the variables was performed.

Results At 12 months, the mean root coverage was 56.48% in the test group and 69.72% in the control group ($p=0.048$), with a 35% and 40% complete root coverage in the xenogeneic collagen matrix and connective tissue graft, respectively. Test group presented less pain (3.65 vs. 5.2 VAS units) ($p=0.015$) and less surgical time (45 vs. 49.15 min) ($p=0.004$) than control group.

Conclusion The use of xenogeneic collagen matrix in RT2 recessions was effective for recession reduction to those obtained using autologous grafts; with the advantage that the duration of surgery and patient morbidity decreased. Therefore, xenogeneic collagen matrix in RT2 recessions could be an alternative to autologous grafts.

Clinical relevance The use of xenogeneic collagen matrix decreases the surgery time and patient morbidity but connective tissue graft results in significantly better mean root coverage and complete root coverage. Xenogeneic collagen matrix can be used in the treatment of RT2 gingival recessions.

Study registration NCT 03344315.

Keywords Collagen matrix · Gingival recession · Connective tissue · Plastic surgery procedures · Clinical trial

Introduction

Gingival recessions are a very common pathology in the adult population [1, 2]. The ideal goal of recession treatment is to achieve complete root coverage (CRC) [3] and good aesthetic results of surrounding soft tissues [4].

In terms of the percentage of mean root coverage (MRC) and CRC, the treatment of choice is the combination of a subepithelial connective tissue graft (CTG) with a coronally advanced flap (CAF) [5–7]. The use of a CTG increases gingival thickness (GT) and achieves long-term stability [8] of the gingival margin [6, 9]. However, obtaining a CTG may cause postoperative complications [10, 11], thus leading to the development of different alternatives, such

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as membranes [12], biological agents [13], and allografts [14]. The objective of these therapies was to find a therapeutic alternative to the use of CTGs, thus allowing the treatment of multiple recessions in a single session, which can reduce surgery times, avoid the need for a second surgery, and improve the color and texture of the tissues [12–16]. This is especially important in patients with periodontitis and multiple recessions with interproximal attachment loss whose treatment is more complex [17].

The use of a xenogeneic collagen matrix (CMX) (Geistlich Mucograft®: Geistlich Pharma, AG, Wolhusen Switzerland) has been proposed as an alternative treatment for regeneration around teeth, obtaining promising results in comparison with CAF alone [6, 18, 19] in achieving greater root coverage and keratinized tissue. These studies have been performed in single and multiple RT1 [20] recessions with different follow-ups and surgical techniques such as CAF or Modified Advanced Coronal Tunneling Advanced (MCAT) [6, 18, 19]. While the percentage of MRC at 12 months with MCAT [21, 22] ranged from 53.2% [21] to 71% [22] the combination of CMX + CAF [8, 15, 23–26] showed better results in root coverage (76.28% [23] – 94.32% [26]).

RT2 [20] recessions are very prevalent in the adult population [6], but the CRC is not always predictable [27]. Although there are clinical studies in which CRC as well as high percentages of MRC have been achieved [28, 29], it is necessary to determine the predictability of treatment with autologous grafts as well as with possible alternative therapies [6, 30], such as the CMX.

Hence, this multicenter clinical trial aimed to compare the clinical efficacy of CMX (Geistlich Mucograft®: Geistlich Pharma, AG, Wolhusen Switzerland) versus a subepithelial CTG when combined to CAF [31] for the treatment of RT2 recessions in terms of percentage of MRC.

Materials and methods

Trial design

This was a randomized, double-blind, multicenter (2-center) clinical trial with a 12-month follow-up period. The study was registered in clinicaltrials.gov (NCT 03344315) and was conducted following the Consolidated Standards of Reporting Trials (CONSORT) guidelines [32]. The study was conducted following the principles of the Declaration of Helsinki (revised in 2013) and was approved by the Euskadi Ethics Committee (CEIC-E) (PI 20,161,008-PS) in February 2017.

The primary aim was to analyze the percentage of MRC associated with the treatment of recessions with CMX (test group) vs. CTG (control group), with the null hypothesis

(H0) that both treatments are equally effective at 12 months. The secondary outcomes were the percentage of CRC, the reduction of recession (REcred) measured in mm, the gain in keratinized tissue width (KTW), the change in GT, patient-related outcome measures (PROMs) regarding post-surgical pain, satisfaction with the treatment and aesthetics perceived by the patient, and aesthetics by a blinded clinical monitor (MVF).

Participants

Reference population

All participants were recruited from two private centers between March 2017 and May 2019. Patients received information about the treatment and the advantages and disadvantages of participating in this study. Informed consent was obtained from all participants before the start of the study.

Inclusion criteria were as follows: (a) patients ≥ 18 years old; (b) periodontally treated and healthy with at least one or more RT2 buccal gingival recessions in incisors, canines, and premolars, located in the same quadrant or sextant with a minimal depth of ≥ 2 mm; (c) full mouth plaque index had to be under 25% [33].

The exclusion criteria were as follows: (a) active periodontal disease; (b) subjects with severe systemic pathology who took or had taken medication that could interfere with the healing of periodontal tissues during the last 6 months.

Sample size calculation

For sample size calculation, the percentage of MRC was considered as the primary outcome to calculate the sample size. To provide a statistical power of 80%, an α -risk of 5%, and an SD = 14, as previously described in the literature [22], 18 patients would be necessary. To account for anticipated dropouts, an additional 10% was added, resulting in 20 patients.

Randomization

To determine the type of graft (CMX or CTG) to be used, the patients were randomized in blocks of two treatments using statistical software (IBM SPSS® Statistics 20.0) (AMGF). The allocation was kept hidden by a clinical monitor (AMGF) until the time of the intervention in opaque envelopes that were opened immediately after flap elevation.

Control of study bias

The clinical examiner (MVF) and the biostatistician (XMM) were blinded to the type of treatment (CMX or CTG). The reproducibility of the clinical examiner (MVF) was determined by evaluating 4 patients (presenting multiple RT2 recessions) not related to the study, at least twice, with a separation of at least 24 h. An intraclass correlation coefficient > 0.85 was considered acceptable.

Intervention: Surgical procedure

All patients initially completed a plaque control program, including oral hygiene instructions [34] to correct habits related to the etiology as well as a presurgical prophylaxis. All the surgeries were performed by two experienced periodontists (LAAZ and ERGP), being the CAF [31] the technique chosen in all cases. The data related to the chair time, defined as the duration of the surgical procedure (in minutes) from the first incision to the last suture was also registered.

After preparing the recipient bed, a CMX (Geistlich Mucograft®: Geistlich Pharma, AG, Wolhusen Switzerland) (test group) or CTG (control group), which was obtained using the UPV/EHU technique [35], was implanted. Both the CMX and the CTG were sutured with absorbable sutures (Ethicon Vicryl® 5/0; Johnson & Johnson); the flap was sutured with Gore-Tex e-PTFE® 5/0 (W.L. Gore & Associates (UK), LTD, Scotland))

Postoperative care included a single presurgical dose of 2 ml of intramuscular betamethasone (Celestone® Cronodose®, Schering Plough S.A., Spain), amoxicillin 875 mg/clavulanic acid 125 mg (Augmentin®, GlaxoSmithKline S.A., Spain) every 8 h for 7 days, analgesics on demand (25 mg dexametoprolfen) and rinses with 0.2% chlorhexidine digluconate (2 times a day for 3 weeks). Also, local cold applications for two days, a soft diet and no physical exercise during the first week after the surgery were advised. Sutures were removed from the palate at 7 days and from the recipient bed at 14 days respectively. At 21 days after surgery, daily brushing was resumed [34].

Monitoring and data collection

At 7, 14 days, 4 weeks, 6, and 12 months patients were scheduled to attend follow-up appointments, which included a professional plaque removal with reinforcement of oral hygiene instructions.

Clinical parameters

At baseline, 6 and 12 months, an experienced, blinded, and previously calibrated examiner (MVF) recorded the following parameters using a standardized periodontal probe (PCP-11, Hu-Friedy, Mfg. Co. LLC, Chicago, USA); the measurements were rounded to the nearest 0.5 mm:

- Recession depth (REC depth): measured in the mid vestibular from the cemento-enamel junction (CEJ) to the deepest point of the pocket. As non-carious cervical lesions were not excluded, if the CEJ was not present or not detectable, it was determined using the technique described by Cairo and Pini-Prato [36] in 2010.
- Recession width (REC width): measured mesio-distally at the level of the CEJ.
- Keratinized tissue width (KTW): measured from the gingival margin to the mucogingival junction.
- Clinical attachment level (CAL), measured from the CEJ to the gingival margin to the deepest point of the pocket (PD + REC depth).
- Percentage of CRC (the number of treated recessions with REC depth = 0 mm): $CRC \times 100/\text{number of recessions}$.
- Percentage of MRC (mean preoperative REC depth - mean postoperative REC depth / mean preoperative REC depth $\times 100$) were calculated.
- GT: measured 3 mm apical from the center of the gingival margin (at baseline and 12 months) using a 25-gauge K endodontic file with a rubber stopper, measured perpendicular to the tooth axis under local anesthesia.

Patient-related outcomes measures

Regarding esthetics, a PROM was carried out using a visual analogue scale (VAS, ranging from 0 to 10) in which patients were asked to score their satisfaction related to their clinical experience (procedure and postoperative pain) at 7 days and esthetic (0 = worst possible aesthetic result and 10 = excellent aesthetic result) at 12 months. Respecting the clinical experience (0 was considered the worst procedure experienced for the patient and 10 the best) and for postoperative pain (0 = no pain and 10 = extreme pain).

Professional esthetic evaluation

Besides the patient's esthetic perception, the esthetics were also assessed from a professional point of view. Thus, one blinded and calibrated examiner (MVF) compared the photographs taken at baseline and 12 months postoperatively.

The assessment was made using the Root Coverage Esthetic Score (RES) [37].

Statistical analysis

All the obtained data were analyzed using statistical software (IBM SPSS® Statistics 20.0; IBM, Chicago, IL, USA), with the patient as the unit of analysis. Initially, the Shapiro–Wilk test was used to evaluate if the distribution was normal or not. First, descriptive statistics were performed, and means and standard deviations were provided for quantitative variables, and percentages were determined for categorical variables. Subsequently, in the analysis of statistical relationships, normality tests led to the use of nonparametric tests for both intragroup (Wilcoxon test of the ranges for related samples) and intergroup comparisons (Mann–Whitney *U*).

Results

The CONSORT diagram, which shows each group and the number of participants, as well as the number of drop-outs, is shown in Fig. 1.

Study population

Twenty patients (13 women (65%)) with a mean age of 48.59 years (SD:10.32), of whom two were smokers (10%) participated in this study. The 96.39% of the participants had multiple recessions. A total of 111 RT2 recessions were treated (CMX: 58 vs. CTG: 53), among which 65 (CMX: 34 vs. CTG: 31) were in the mandible (58.5%). A total of 31 incisors (27.92%), 36 canines (32.43%), and 44 premolars (39.63%) were included. REC depth, REC width, KTW, GT, and CAL at baseline are shown in Table 1.

Clinical results

Clinical results at 6 months are summarized in Table 2. When analyzing the intergroup results, no significant differences were observed in any of the parameters analyzed. Clinical results at 12 months are reported in Tables 2 and 3, and 4; the changes between 6 and 12 months are shown in Table 3.

The percentage of MRC was 56.48% on test and 69.72% on control sites at 12 months ($p=0.048$). Between 6 and 12 months, the percentage of MRC decreased from 59.60 to 56.48% in the test group

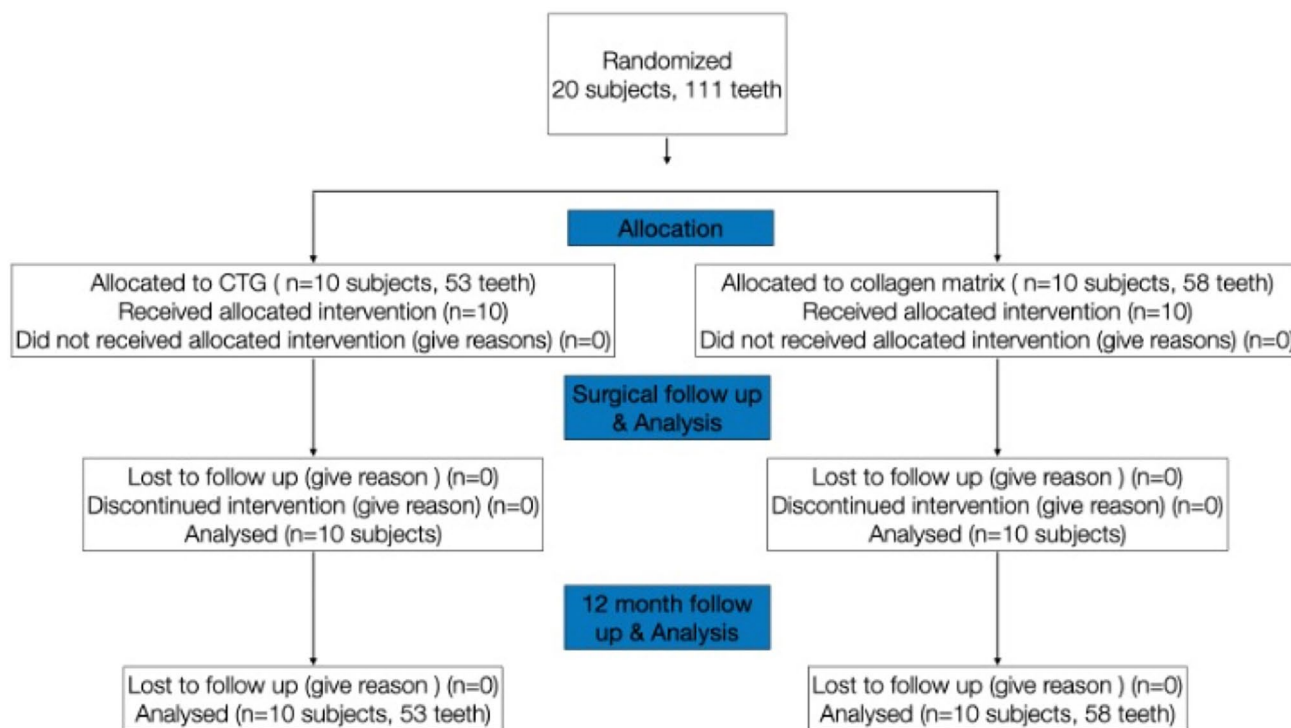


Fig. 1 CONSORT diagram

Table 1 Baseline characteristics of the study population

	Test (CMX) (n=0)	Control (CTG) (n=20)	P value	Total
Age (mean ± SD)	48.79 ± 10.35	48.39 ± 10.59	0.73	48.59 ± 10.32
Females n (%)	13 (65%)	13 (65%)	> 0.05	13 (65%)
Smokers n (%)	1 (5%)	1 (5%)		2 (10%)
REC per patient (mean ± SD) [range]	2.9 ± 1.12 [1–5]	2.65 ± 0.99 [1–4]	0.622	2.78 (1.05) [1–5]
REC maxilla n (%)	24 (41.38%)	22 (41.51%)	> 0.05	46 (41.44%)
REC mandible n (%)	34 (58.62%)	31 (58.49%)		65 (58.5%)
REC depth (mm) (mean ± SD) [range]	3.69 ± 1.03 [2.25–5.5]	3.67 ± 0.66 [2.25–4.75]	0.968	3.68 ± 0.85 [2.25–5.5]
REC width (mm) (mean ± SD) [range]	4.15 ± 0.73 [2.75–5.5]	3.91 ± 0.68 [2.5–5.5]	0.289	4.03 ± 0.71 [2.5–5.5]
CAL (mm) (mean ± SD) [range]	4.88 ± 1.12 [3.33–7]	4.95 ± 0.75 [3.25–6.5]	0.565	4.91 ± 0.95 [3.25–7]
KTW (mm) (mean ± SD) [range]	1.78 ± 1.24 [0–5]	1.77 ± 1.10 [0–4]	0.968	1.78 ± 1.24 [0–5]
GT (mm) (mean ± SD) [range]	1.09 ± 0.28 [0.5–2]	1.19 ± 0.29 [1–2]	0.365	1.14 ± 0.29 [0.5–2]

REC depth (Recession depth); REC width (Recession width); KTW (keratinized tissue width); CAL (Clinical attachment level); GT (Gingiva thickness); SD (standard deviation); mm (millimeters); CMX (xenogeneic collagen matrix); CTG (connective tissue graft)

Table 2 Clinical results at baseline (T0), six (T1) and twelve (T2) months

Grupo		T ₀ (baseline) (mean ± SD)	T ₁ (6 months) (mean ± SD)	T ₂ (12 months) (mean ± SD)	T0-T1 P intragroup	T0-T2 P intragroup	T1-T2 P intragroup
RECdepth (mm)	Test (CMX) n=20	3.69 ± 1.03	1.48 ± 0.73	1.55 ± 0.77	< 0.001	< 0.001	0.448
	Control (CTG) n=20	3.68 ± 0.66	1.18 ± 0.88	1.11 ± 0.78			0.905
P (intergroup)		0.968	0.314	0.149	-	-	-
RECwidth (mm)	Test (CMX) n=20	4.15 ± 0.74	2.83 ± 1.02	2.9 ± 0.94	< 0.001	< 0.001	0.866
	Control (CTG) n=20	3.91 ± 0.69	2.38 ± 1.56	2.48 ± 1.58			0.767
P (intergroup)		0.289	0.478	0.583	-	-	-
KTW (mm)	Test (CMX) n=20	1.79 ± 1.25	2.36 ± 2.47	1.96 ± 1.09	0.307	0.443	0.623
	Control (CTG) n=20	1.78 ± 1.11	2.47 ± 1.3	2.43 ± 1.17	0.004	0.01	0.752
P (intergroup)		0.968	0.301	0.242	-	-	-
CAL (mm)	Test (CMX) n=20	4.88 ± 1.12	2.53 ± 0.78	2.64 ± 0.79	< 0.001	< 0.001	0.14
	Control (CTG) n=20	4.95 ± 0.76	2.35 ± 0.96	2.28 ± 0.87			0.284
P (intergroup)		0.565	0.738	0.265	-	-	-

REC depth (Recession depth); REC width (Recession width); KTW (keratinized tissue width); CAL (Clinical attachment level); SD (standard deviation); mm (millimeters); CMX (xenogeneic collagen matrix); CTG (connective tissue graft)

Table 3 Results of clinical changes at six (T1) and twelve (T2) months

Clinical parameter	Group	T1	T2	P intragroup
		(6 months)	(12 months)	
MRC (%)	Test (CMX) <i>n</i> =20	59.60 ± 16.23	56.48 ± 19.68	0.167
	Control (CTG) <i>n</i> =20	68.70 ± 23.53	69.72 ± 21.21	0.378
<i>P</i> intergroup		0.163	0.048	
CRC (%)	Test (CMX) <i>n</i> =20	45	35	0.084
	Control (CTG) <i>n</i> =20	40	40	0.086
<i>P</i> intergroup		0.64	0.14	
RECCred (mm)	Test (CMX) <i>n</i> =20	2.21 ± 0.90	2.14 ± 1.07	0.448
	Control (CTG) <i>n</i> =20	2.50 ± 0.84	2.56 ± 0.86	0.905
<i>P</i> intergroup		0.277	0.181	
CAL gain (mm)	Test (CMX) <i>n</i> =20	2.36 ± 0.97	2.64 ± 0.79	0.14
	Control (CTG) <i>n</i> =20	2.60 ± 1.10	2.28 ± 0.87	0.284
<i>P</i> intergroup		0.512	0.221	
KTW gain (mm)	Test (CMX) <i>n</i> =20	0.57 ± 2.08	0.18 ± 0.84	0.623
	Control (CTG) <i>n</i> =20	0.69 ± 0.85	0.65 ± 0.92	0.752
<i>P</i> intergroup		0.174	0.114	
GT (mm)	Test (CMX) <i>n</i> =20	-	0.46 ± 0.54	-
	Control (CTG) <i>n</i> =20	-	0.78 ± 0.47	-
<i>P</i> intergroup		-	0.038	

MRC (mean root coverage), CRC (complete root coverage), RECCred (reduction in recession); KTW (keratinized tissue width); CAL (Clinical attachment level); GT (Gingival thickness); SD (standard deviation); % (percentage); mm (millimeters); CMX (xenogeneic collagen matrix); CTG (connective tissue graft)

and an increased in the control group from 68.70 to 69.72%, respectively. The CRC was achieved in 7 patients (35%) in the test group and 8 patients (40%) in the control group. Three patients presented with CRC for all treated recessions in the control group. At the recession level, the percentage of CRC decreased in the test group (from 15.5 to 12.1%), and in the control group, it increased from 18.9 to 22.6% from 6 to 12 months.

Both treatment groups showed significant post-surgical improvement in all clinical variables, except for the KTW in the test group. The GT increased after the surgical procedures: 0.46 mm (SD:0.54) in the test group and 0.78 mm (SD:0.47) in the control group ($p=0.038$).

An analysis was performed by the treatment group (test group or control group) and the results are summarized in Table 4. Statistically significant differences were observed

for all parameters (except KTW and GT) in the control group between the upper and lower jaws, with favorable results for the maxilla; in the test group, the differences between the maxilla and mandible were only significant for the increase in GT.

Results of the surgical procedure and PROMs

No postoperative complications were observed after any surgery. The results are reported in Table 5. The mean surgical time was 45 min (SD:9.01), i.e., 41 min (SD:7.6) (CI 95% 37.41–44.59) in the test group and 49.15 min (SD:8.5) (CI 95% 45.15–53.15) in the control group; the differences between groups were significant ($p=0.004$).

Regarding the assessment of pain, less pain was reported by patients who received CMX, with a VAS=3.65 (SD:2.08) (95% CI 2.67–4.63) vs. VAS=5.2 (SD:2.31) (95% CI 4.12–6.28) ($p=0.015$). Patients in the test group were more

Table 4 Clinical results in maxilla and mandible at 12 months of follow-up

Parameter T ₂	Location	CMX	CTG	p intergroup
MRC (%)	Maxilla (n = 9)	65.01 ± 16.83	83.34 ± 15.68	0.015
	Mandible (n = 11)	49.49 ± 19.74	58.58 ± 18.83	0.141
p intragroup		0.152	0.007	
CRC n (%)	Maxilla (n = 9)	55.56	77.78	0.034
	Mandible (n = 11)	27.28	9.09	0.72
p intragroup		0.412	0.012	
REC depth (mm) (mean ± SD)	Maxilla (n = 9)	2.61 ± 0.97	3.15 ± 0.73	0.297
	Mandible (n = 11)	1.76 ± 1.06	2.08 ± 0.67	0.217
p intragroup		0.08	0.003	
REC width (mm) (mean ± SD)	Maxilla (n = 9)	1.6 ± 0.99	2.5 ± 1.48	0.19
	Mandible (n = 11)	0.97 ± 0.89	0.57 ± 0.78	0.332
p intragroup		0.147	0.001	
KTW gain (mm) (mean ± SD)	Maxilla (n = 9)	0.16 ± 1.09	0.87 ± 1.07	0.185
	Mandible (n = 11)	0.19 ± 0.63	0.46 ± 0.77	0.401
p intragroup		0.943	0.33	
CAL gain (mm) (mean ± SD)	Maxilla (n = 9)	2.67 ± 0.97	3.47 ± 0.88	0.222
	Mandible (n = 11)	1.89 ± 1.07	2.01 ± 1.03	0.562
p intragroup		0.08	0.004	
GT gain (mm) (mean ± SD)	Maxilla (n = 9)	0.81 ± 0.55	0.97 ± 0.48	0.481
	Mandible (n = 11)	0.17 ± 0.31	0.64 ± 0.44	0.034
p intragroup		0.004	0.135	

MRC (mean root coverage), CRC (complete root coverage), RECred (reduction in recession); KTW (keratinized tissue width); CAL (Clinical attachment level); GT (Gingiva thickness); SD (standard deviation); % (percentage); mm (millimeters); CMX (xenogeneic collagen matrix); CTG (connective tissue graft)

Table 5 Patient based surgical parameters and patient perception during the surgery

	Test (CMX)	Control (CTG)	inter-group
	N=20 (mean ± SD)	N=20 (mean ± SD)	P
Surgical time (minutes)	41 ± 7.6	49.15 ± 8.5	0.003
RES	6.74 ± 1.97	7.29 ± 2.24	0.309
PROMs			
VAS postoperative pain	3.65 ± 2.08	5.2 ± 2.31	0.015
VAS clinical experience	6.4 ± 2.21	5.35 ± 2.08	0.134
VAS aesthetic	6.85 ± 1.5	7.15 ± 1.3	0.64

Surgical time: duration of the surgical procedure (in minutes); RES (root coverage esthetic score), PROMs: clinical experience using a visual analog scale (VAS) (0 being the worst procedure and 10 the best); postoperative pain using a visual analog scale (VAS) (0 being the least pain and 10 being the maximum pain). Aesthetic result as assessed by the patient using a visual analog scale (VAS) (0=worst possible aesthetic result and 10=excellent aesthetic result) SD (standard deviation); mm (millimeters); CMX (xenogeneic collagen matrix); CTG (connective tissue graft)

satisfied with the procedure in general, but the differences between groups were not significant.

The aesthetic evaluation score at 12 months was 6.85 (SD:1.5) in the test group and 7.15 (SD:1.3) in the control group These values were similar to the RES

score in the test group (6.7 (SD:1.97)) and in the control group (7.28 (SD:2.24)).

Clinical and radiographic characteristics and surgical procedures of one patient from test group and control group at baseline and 12 months are shown in Figs. 2 and 3.

Discussion

To our knowledge, there is no double-blind randomized clinical trial in the literature that compares the use of a soft tissue substitute such as the CMX vs. the CTG for the treatment of RT2 recessions in combination with CAF, thus making it difficult to compare our results with recent evidence [6, 27, 30].

The results of this study indicated that the percentage of MRC was lower in the test group than in the control group (CMX: 56.48% vs. CTG: 69.72%) (p=0.048) and that the percentage of CRC was lower in the test group than in the control group (35% vs. 40%) after 12 months; therefore, hypothesis (H0) is rejected.

Our results partially coincide with a recent meta-analysis of Miller classes I and II recessions [18, 38], in which lower MRC were observed with CMX compared with CTG, with similar CRC in both study groups.

Fig. 2 Surgical intervention in a patient allocated to the CAF+CMX group. (a)(b) clinical and radiographic features at baseline, (c) Intra-operative view: CMX, (d) Immediate postoperative view: coronally flap advancement and closure, (e)(f) Outcome at 12-months follow-up

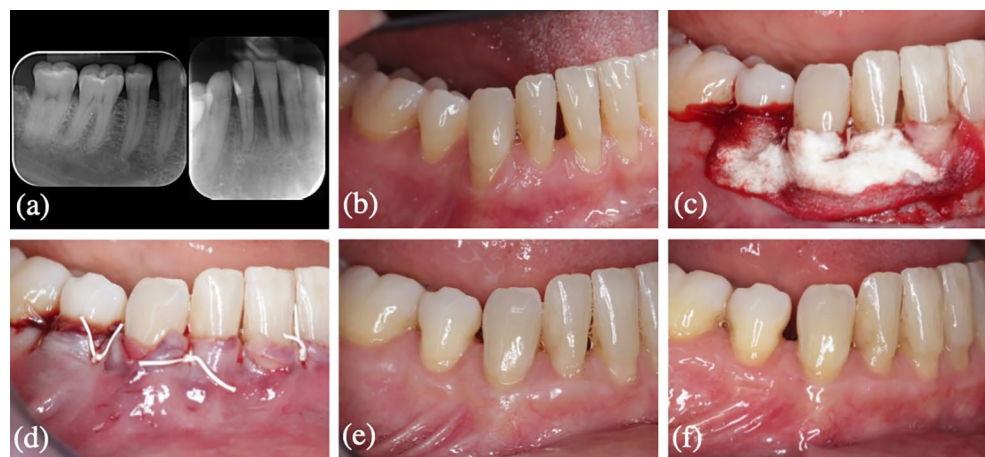
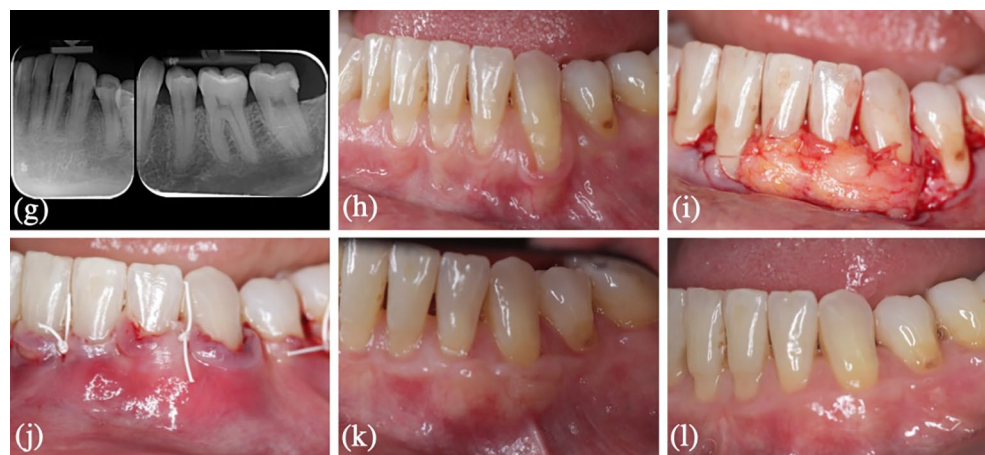


Fig. 3 Surgical intervention in a patient allocated to the CAF+CTG group: (g)(h) clinical and radiographic features at baseline, (i) Intra-operative view: CTG (j) Immediate postoperative view: coronally flap advancement and closure (k)(l) Outcome at 12-months follow-up



However, the percentage of MRC (CMX:56.48% vs. CTG: 69.72%) ($p=0.048$) and the percentage of CRC (CMX:35% vs. CTG: 40%) results for both treatment groups were within the ranges reported in previous studies of RT2 recessions with CAF+CTG at 12 months (54.8–77.57%) [39–41]. Only, Fernández-Jiménez et al. [40], 2023, evaluated the CRC at 12 months in multiple recessions with results (50%) that were slightly superior to those herein (40%) where the KTW at baseline was higher.

The evidence regarding CMX is limited to RT1 recessions where different treatments have been compared: (a) CAF+CTG vs. CAF+CM [8, 15, 26] (b) CAF vs. CAF+CM [23–25, 42, 43]; (c) Modified Coronally Advanced Tunnel (MCAT)+CTG vs. MCAT+CM [22, 23]. The percentage of MRC with CMX at 12 months ranged from 76.2% [23] to 94.32% [24]. Our results were lower (56.48%) than the current evidence, probably due to the type of recessions treated in this clinical study (RT2) where attachment loss was present. Also, only three studies until now have treated multiple recessions [8, 24, 25] with CAF+CMX, and CRC was evaluated in five studies previously [8, 24–26, 42] and it ranged from 36% [42] to 72% [24]. Although these results were superior to those obtained

in our study (35%), they are not comparable due to the type of recessions treated, where the REcred as well as KTW gain should be considered a treatment success in the treatment of gingival recessions associated with loss of interproximal attachment [44, 45].

In Chambrone's 2010 meta-analysis [46], for the treatment of RT1 recessions, in studies with more than 10 patients, at 6 months, the CTG yielded very heterogeneous results, with percentages of MRC (64.5–97.3%) and percentages of CRC (10–96.1%) values that coincide with a previous review [3]. Therefore, our MRC results (CMX: 56.48% vs. CTG: 69.72%) for RT2 recessions are encouraging. However, CRC (CMX: 35% vs. CTG: 40%) is far from the results for recessions without insertion loss, which was expected based on evidence in the literature [6].

A recent CRC meta-analysis of 37 publications about these types of recessions [27] found wide CRC ranges (32.87–63.82%). Achieving CRC for these types of recessions is considered a challenge because of interproximal attachment loss [47], which implies an increase in the avascular surface [26, 48]. Our results are consistent with those previously reported [49] of Miller class III recessions treated with modified tunnel technique (TTM) in combination with

CTG, where differences between the MRC (83%) and the CRC (40%) were reported. The differences with our results in MRC could be due to the surgical technique [39] and/or the characteristics of the sample (our recessions were wider and had a lower KTW).

Advantages of using alternative materials include the reduction in intraoperative time and patient morbidity [8], findings that were confirmed in this RCT. A reduction in surgical time of 8 min was observed in our study, less than that obtained in a recent study [50], where RT1 recessions were treated (15 min).

Patient satisfaction was generally higher in the test group, which also presented lower morbidity ($p=0.015$); these findings confirm previous results [8], in which the recovery time of patients was shorter (1.8 days) in the CMX group, thus favoring a better assessment of the treatment received.

Another objective of these procedures is to increase keratinized tissue [18], which is key in recessions with fine phenotypes and in maintaining the GM in the long term [51, 52]. It has been reported that KTW gains are higher with CTG than with CMX, but without being significant [18], which coincides with our results at 6 months, but not at 12 months, where a greater decrease in KTW was observed in the CMX group. The evidence for increased GT with CMX vs. CTG is limited [25]; in this study, at 12 months, there was a trend for increased GT with the CTG (0.32 mm, $p=0.056$), coinciding with a difference of 0.23 mm in favor of CTG in the study by Cardaropoli et al. [26]. In the CMX group, the thickness gain was greater in the upper maxilla ($p=0.004$), unlike in the control group, where the differences between the maxilla and mandible were not significant.

The main indication for the treatment of recessions is aesthetic demand [53]. There is no consensus on which approach yields more aesthetic results concerning CRC or the similarity of treatment tissue with adjacent tissue [4, 45]. In our study, the aesthetic assessment by the patients was high and similar in both groups (CMX: 6.85 (SD:1.5) vs. CTG: 7.15 (SD:1.3)), a finding that coincides with previously reported results [24], where no differences were observed between groups. In contrast, a recent study obtained a more natural texture and contour with CMX than with a CTG [54]. When the professional assessment was performed the RES was similar between groups (CMX: 6.70 (SD:1.97) vs. CTG: 7.28 (SD:2.24)) and comparable to results reported in the literature [23], i.e., RES of 7.85 (SD:2.42) for CMX and 7.34 (SD:2.90) for CTG. Therefore, both treatment modalities achieved satisfactory aesthetic results for both professionals and patients.

Although this RCT shows new and relevant information on the treatment of RT2 recessions, it is not exempt from limitations. First, there was the lack of assessment of the flap thickness margin in surgery or the presence of detectable

step or CEJ whose importance has been evidenced in the recent 2018 classification. Also, the soft tissue outcomes were assessed at 12 months, so long-term observations are necessary to confirm these results. However, this is the first double-blinded RCT in RT2 recessions that compares a CMX and autogenous grafts, including both maxillae (mandible:58.5%), and multiple recessions (96.39%).

Conclusions

Within the limitations of this clinical study, although MRC was greater with CTG we conclude that CMX is a treatment option for these challenging RT2 recessions. The surgical time and patient morbidity were reduced in the test group. Therefore, CMX can be considered an alternative to autologous grafts.

It is necessary to perform more RCTs in patients with periodontitis due to the high prevalence of multiple recessions in these patients, which require large grafts that entail greater postoperative morbidity.

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Data availability No datasets were generated or analysed during the current study.

Declarations

Ethics approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1975 Helsinki Declaration (revised in 2013) and its later amendments or comparable ethical standards.

Consent to participate Informed consent was obtained from all individual participants included in the study.

Competing interests The authors declare no competing interests.

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