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Conventional versus flap-protected free gingival graft: a multicenter randomized clinical trial

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Abstract: The purpose of this study was to compare the outcomes of a modified gingival graft technique, in which the released flap is positioned and sutured over the graft, with the conventional free gingival graft (FGG) procedure, when both are used for gingival augmentation. A 12-month, multicenter parallel randomized controlled trial was conducted. Subjects with buccal RT2 gingival recessions and keratinized tissue width (KTW) < 2 mm in at least one mandibular incisor were randomized to control group (n = 20; conventional FGG) or test group (n = 20; modified FGG; flap sutured over FGG using sling sutures). The primary outcome (KTW) was measured at baseline and after 3, 6 and 12 months, as was keratinized tissue thickness (KTT). Postoperative pain (POP) and analgesic intake were also recorded. Both techniques promoted a significant increase in KTW and KTT when compared to baseline ($p < 0.05$) with no significant differences between groups (KTW change of 6.1±1.5 mm and 5.4±1.6 mm, for control and test, respectively; p=0.16). However, test group patients reported less POP after 7 days and used less analgesic medication than control group patients ($p < 0.05$). We concluded that the modified FGG was comparable to conventional FGG in augmenting keratinized tissue width and thickness at mandibular incisors, but resulted in less patient morbidity.

Keywords: Gingival Recession; Transplants; Pain, Postoperative; Wound Healing.

Introduction

The role of keratinized tissue (KT) on periodontal health maintenance has been debated for many years. Lang and Löe[1] reported that areas with < 2 mm of attached gingiva exhibited inflammation and exudate, despite biofilm absence. It has also been reported that lack of KT may prevent adequate oral hygiene because of discomfort during toothbrushing, both around teeth[2] and dental implants.[3,4]

The 2017 Workshop on the Classification of Periodontal Conditions[5] established that any amount of gingiva is sufficient for periodontal health maintenance, when optimal oral hygiene is achieved. However, many patients cannot attain an adequate level of biofilm control,[6] mainly when KT is absent. Moreover, restorative[7-9] treatment may further hinder optimal

biofilm control and aggravate gingival inflammation. Thus, soft tissue augmentation around teeth[10] and dental implants[11] may be considered when anatomical conditions (KT < 2 mm; thin periodontal phenotype) are likely to predispose to gingival inflammation. Furthermore, gingival augmentation procedures have been shown to reduce existing or prevent future gingival recession (GR) around teeth.[12]

Free gingival graft (FGG) is considered the "gold standard" for gingival augmentation procedures.[10] Despite its high clinical success rate, the conventional FGG technique[13] has limitations. Graft shrinkage, especially in width, occurs during healing and can result in loss of up to half of the original apico-coronal graft dimension.[14-16] Poor color matching compared to adjacent tissues restricts this technique to mandibular sites.[17,18] Postoperative pain is highly prevalent, primarily at the palatal donor site,[19-21] but also at the recipient site.[19] These limitations suggest that there is opportunity to improve the conventional FGG technique to ameliorate both clinical and patient-reported outcomes.

With the objective of improving FGG outcomes, Duarte and Castro[22] proposed a modification on the original technique, using the tissue reflected during recipient bed preparation to cover and additionally stabilize the graft sutured at the recipient site. According to these authors, the proposed modification could favor early healing, decrease FGG shrinkage and improve color matching with surrounding tissues. However, there was no information on patient-reported outcomes. So far, no randomized trial compared the outcomes of the conventional versus the modified FGG technique. Therefore, the aim of this investigation is to test whether the flap-protected FGG technique of Duarte and Castro[22] might improve the clinical performance of the conventional FGG technique.

Methodology

Study design

This was a multicentric, 2-arms, parallel randomized controlled clinical trial. It was conducted at the School of Dentistry of the University of São Paulo - USP (coordinator center) and at the State University of Maringá - UEM. The protocol followed the SPIRIT guidelines,[23] was approved by the Institutional Review Board of both the University of São Paulo (protocol 1.070.718) and State University of Maringá (protocol 1.963.631) and was registered at clinicaltrials.gov (protocol NCT02613702).

Eligibility criteria

Inclusion criteria: systemically healthy adults > 18 years; indication for FGG treatment at mandibular incisor area (*i.e.*, difficulty or discomfort during oral hygiene; gingival margin mobility; high muscle attachment and/or frenum pull; shallow vestibule and gingival recession); KT width (KTW) < 2 mm in at least one of four mandibular incisors; RT2 recession at primary experimental tooth and adjacent teeth; recession at primary experimental tooth and adjacent teeth should have ≤ 2 mm of discrepancy.

Exclusion criteria: RT3 recession;[24] single deep gingival recession; caries or non-carious cervical lesions at recipient sites; severely malpositioned teeth; teeth with residual probing depth ≥ 4 mm, mobility ≥ 1; vertical bone loss; smokers or former smokers; pregnant or lactating women; systemic disease or any other condition that could impair gingival healing; patients ASA III or higher (American Society of Anesthesiologists).

Procedures and interventions

Participants received oral hygiene instructions and scaling according to individual needs. Study surgery was performed when patients achieved overall PI and GI < 20% and local PI = 0. KTW was measured at primary experimental tooth and adjacent teeth; tooth with lowest KTW was designated as primary experimental tooth and neighboring incisor with second lowest KTW was designated as "adjacent" tooth. Patients were randomly assigned to Control Group (CG - conventional technique) or to Test Group (TG - modified technique).

Surgeon calibration

Two experienced periodontists performed all procedures (JBCN at São Paulo; COS at Maringá). Before the experimental phase, the surgeons operated four pilot cases together. During treatment

of the pilot cases all details were discussed and a step-by-step surgical manual was prepared to be followed during study procedures. The manual included clinical photographs and illustrations of each surgical step with details on suture number and position. During the study, a monitor from the coordinating center (São Paulo) visited the collaborating center (Maringá) twice, to verify consistency of procedural steps.

Surgical procedures

FGG harvesting was identical for both groups. Only details of recipient site preparation and graft stabilization differ between techniques.

Conventional technique – Control group

Preoperatively, intraoral antisepsis with 0.2% chlorhexidine digluconate and extra-oral antisepsis with 2.0% chlorhexidine digluconate were performed. At recipient and donor sites, anesthesia was established with 2% mepivacaine and 1:100,000 epinephrine. Procedures were timed starting immediately before placement of first incision.

Recipient site was delimited by a horizontal incision of 14 mm in length, positioned 3 mm apically from the tip of the shortest papilla. This incision started 3 mm laterally to the primary experimental tooth and extended to the adjacent tooth. Then, two vertical incisions of 7 mm delimited the lateral and apical extent of the recipient site (Figure 1). A split thickness flap was then elevated and an internal horizontal incision was made at the periosteum, 10 mm apical to the first horizontal incision, to minimize the effect of muscle insertion at the recipient site (Figure 1). All incisions were made using 15c blades. In the conventional technique, the elevated partial thickness flap that initially covered the recipient site was totally excised. This step was always performed immediately before graft stabilization and right after opening the opaque envelope that revealed group allocation.

A custom metallic rectangular template (14 mm x 7 mm) was used to delineate the FGG to be harvested.[16] The template was pressed on the palate and incisions were made to an approximate depth of 2.0 mm, following the template limits. Donor sites received a collagen sponge (Hemospon, TechNew Com. Ind. Ltda., Rio de Janeiro, Brazil) and sutures (4.0 silk) anchoring at buccal aspects of neighboring teeth.

Harvested grafts were immediately trimmed to a thickness of approximately 1.5 mm (trimming always performed from the connective tissue side) and placed on the recipient site. Grafts were then secured by four single interrupted sutures, one at each papilla and one at each side, at the level of mucogingival junction (Figure 1). Two additional suspensory periosteal sutures, one per experimental tooth, were applied, secured on the lingual aspect of the two experimental teeth. The graft was then gently pressed on the recipient bed for 3 min; periodontal dressing was not used.

Modified yechnique – Test group

The modified surgical technique differed from the conventional procedure in the following aspects: a) the flap elevated during recipient bed preparation was preserved, i.e., not discarded; b) the suspensory periosteal sutures were not applied over the otherwise secured graft; c) the released flap was coronally positioned and sutured over the graft using two suspensory sutures (Figure 1). All sutures applied, in both techniques, were 5.0 nylon monofilament (Ethicon, Johnson & Johnson, São José dos Campos, Brazil), since no sutures were covered by the flap.

Postoperative protocol

The following postoperative instructions were given: 750 mg Paracetamol (prescribed), every 6 hours, as needed for pain control; abstinence from any mechanical plaque control in the operated area for three weeks; use of antimicrobial mouthrinse (0.12% chlorhexidine, prescribed) twice daily. Donor and recipient site sutures were removed after 7 and 21 days, respectively. At 21 days, a surgical toothbrush (Curaprox CS Surgical, Curaden AG, Kriens, Switzerland) was given to each patient, along with instructions for proper use. At 42 days, TG subjects received professional dental cleaning and a superficial debridement to eliminate any occasional soft tissue tunnels and adherences when needed. Patients were scheduled for periodontal maintenance and examination at 3, 6 and 12 months

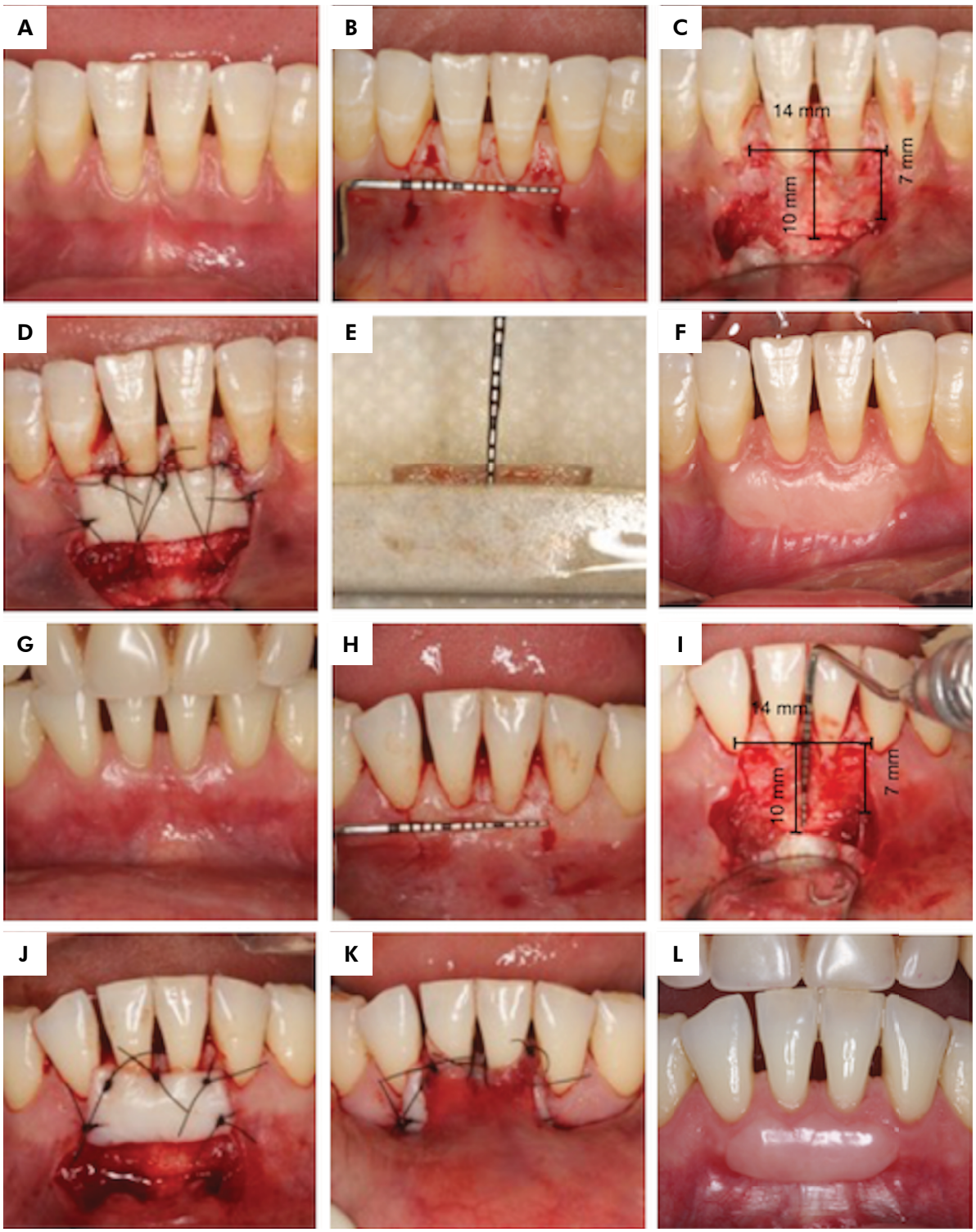

Figure 1. Surgical technique and 12 months follow up. Figures A to D: Control group surgical technique, representative patient. Figure E: Standardized FGG. Figure F: 12 months follow up of same control group patient. Figures G to K: Test group surgical technique. Figure L: 12 months follow up of same test group patient.

after surgery. Manual toothbrushes were given to all patients at the same postoperative time points and they were motivated to continue applying the oral hygiene instructions they received in the beginning of the study.

Outcomes

Clinical parameters were measured by two trained and calibrated examiners (VCA in São Paulo; ROL in Maringá), one in each center. A UNC-15 periodontal probe was used to measure: probing depth (PD), clinical attachment level (CAL), gingival recession (GR), Plaque Assessment Scoring System (PASS)[25] and bleeding on probing (BoP), at baseline and after 3, 6 and 12 months.

Primary outcome

The primary outcome was mean apical-coronal width of KT (KTW) after 12 months, measured at the mid-buccal aspect of the main experimental tooth.

The mandibular incisor area mucosa was stained with Schiller's iodine solution to identify the mucogingival junction. Subsequently, the distance between gingival margin and mucogingival junction was measured with a compass on the mid-buccal of each experimental tooth, parallel to the long axis. The compass opening was then measured with a digital caliper and recorded. This parameter was evaluated at baseline, and at the 3-, 6- and 12-month follow-ups.

Secondary outcomes

a. *KT Thickness (KTT)*: measured with a finger spreader associated with a silicone stop. The finger spreader was pressed perpendicularly to the alveolar bone, 2 mm apical to the gingival margin, at the center of 'experimental' and 'adjacent' teeth. The silicone stop was gently positioned on buccal soft tissue. KTT was considered the distance between the tip of the finger spreader and the silicone stop and was measured with a digital caliper[26] (baseline, 3, 6 and 12 months after surgical procedure).
b. *Vertical Shrinkage (VS)*: to calculate vertical shrinkage of the graft, the KTW change was used (KTW at 12 months subtracted from KTW at baseline). As all grafts measured 7 mm in vertical length, the following formula was used: [7 - KTW change/7].100[14].
c. *Postoperative Pain (POP):* Visual Analog Scale (VAS) was used to measure POP at recipient and donor sites at the following time points: 7, 14, 21 and 28 days. The VAS was represented by a horizontal line of length of 100 mm. A hundred was considered maximum pain.
d. *Analgesic intake (AI):* number of painkillers consumed after surgery.
e. *Patient's satisfaction (PS)*: after 6 and 12 months, patients were asked to use 0-10 VAS to report their satisfaction with recipient site aesthetics, in which 10 represented maximum satisfaction.
f. *Need of superficial mucosal debridement (SMD, only for TG)*: recipient areas were analyzed 42 days postoperatively and considered eligible for SMD according to the following criteria: presence of clinically detectable soft tissue adhesions with tunnel or mucosal tissue connection close to the gingival margin resulting in < 3 mm of KTW (Figure 2). When needed, SMD was performed using microscissors and/or 15c blades, after establishment of local anesthesia; sutures, dressing, or medications were not used after SMD. Cases that presented with ≥3 mm of KTW and without soft tissue adhesions over the graft were considered "without need of SMD".

Calibration

Intra- and inter-examiner reproducibility and calibration for KTW and KTT were conducted by two repeated examinations in four subjects, with 7 days of interval between them. For KTW, inter-examiner reproducibility was 0.784 (0.545 - 0.932) and intra-examiner reproducibility was 0.802 (0.633 - 0.898) (VCA) and 0.984 (0.968 - 0.992) (ROL). For KTT, inter-examiner reproducibility was 0.835 (0.623 - 0.961) and intra-examiner reproducibility was 0.982 (0.964 - 0.991) (VCA) and 0.882 (0.780 - 0.971) (ROL).

Sample size calculation

Sample size was calculated with G*Power (Version 3.1, Universitat Kiel, Germany) considering an expected inter-group difference of 0.5 mm for mean KTW after 12 months, a standard deviation of 0.6

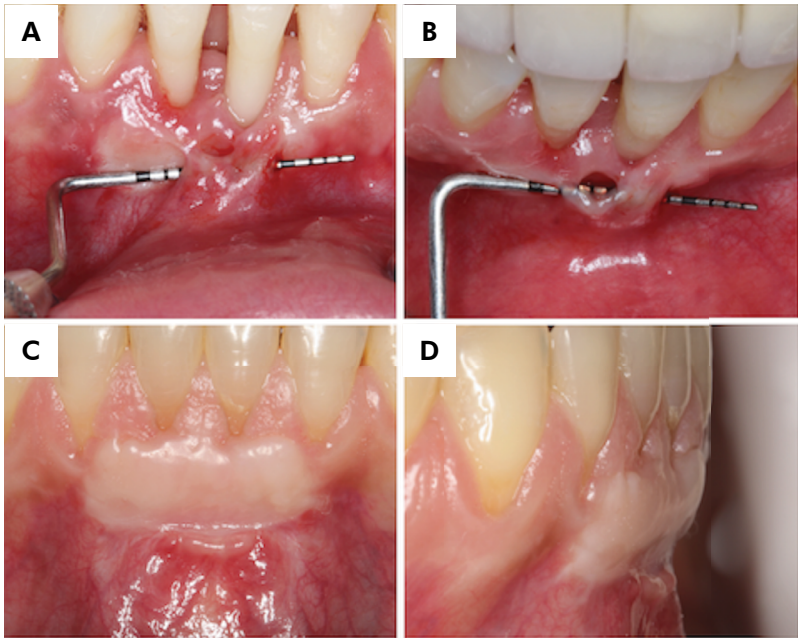

Figure 2. Test group recipient sites 42 days postoperatively. Buccal (A) and occlusal (B) view of soft tissue tunnel from patient who needed superficial mucosal debridement (SMD). Buccal (C) and lateral (D) view from patient who did not need SMD.

mm, alpha of 5% and power of 80% (one-tailed test), resulting in 18 patients per group being required. Considering 10% of drop-out, 40 patients (20 per group) were recruited.

Randomization

Random sequence was generated by an investigator (CMP) not involved in patient inclusion or treatment, using a software (Random Allocation Software 2.0), with random blocks of 2 and 4. Randomization was stratified according to study center. Participants were enrolled by VCA at USP and ROL at UEM. Allocation concealment was implemented with sequentially numbered opaque sealed envelopes. In each center, envelopes were opened during surgery, just before graft suturing.

Blinding

This was a double-blind study. Neither subjects nor examiners were aware of the technique performed by surgeons.

Statistical analysis

For quantitative variables, data are expressed as mean and standard deviation. Statistical analysis was conducted using an intention-to-treat approach. Normality was verified with Shapiro-Wilk test, and homoscedasticity was verified with Levene test. Treatment effects were estimated using generalized linear models (Repeated measures ANOVA), in which center and treatment were considered factors. *Post hoc* Newman-Keuls test was used to compare groups and time points for the following parameters: PD, CAL, GR, PASS, BoP, KTW, KTT and POP. Independent samples t test was used to compare groups regarding VS, AI, PS and change in KTT. A p value < 0.05 was considered significant.

Results

Three hundred subjects were examined from September 2015 to June 2017 and 40 were included (CG, n = 20; TG, n = 20), 26 at USP and 14 at UEM. All patients concluded the study (Figure 3). There were no significant differences between groups for demographic variables (Table 1). After non-surgical periodontal treatment, there was no difference ($p > 0.05$) between groups regarding baseline parameters (PD, BoP, CAL) at buccal aspect of

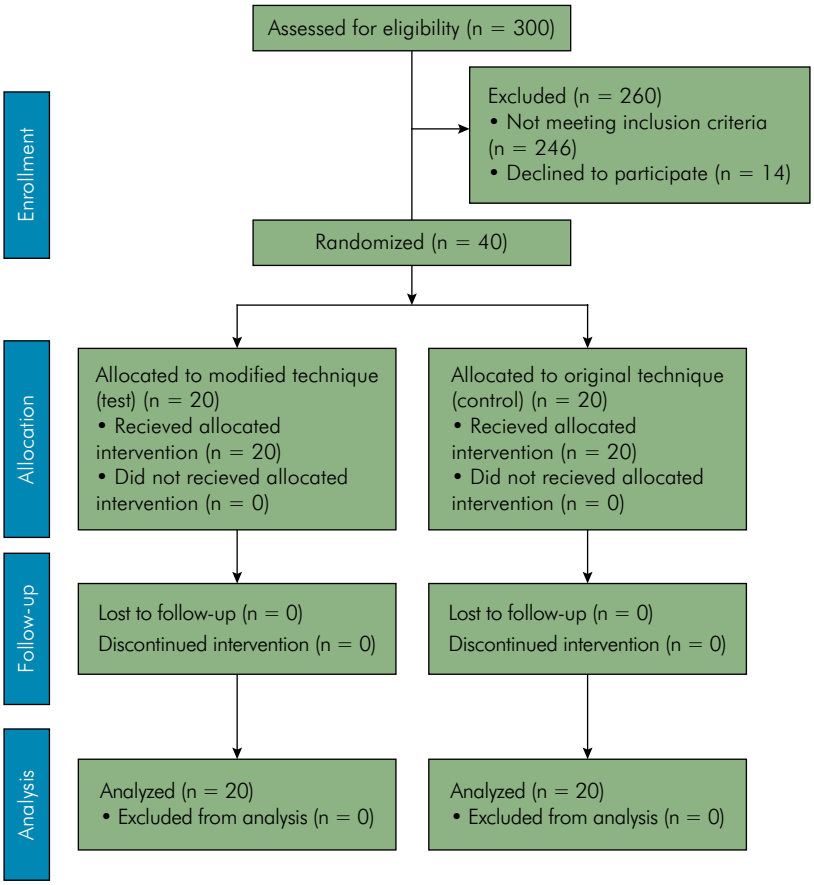

Figure 3. Consort flowchart of the study.

Table 1. Demographic and clinical outcomes at baseline,

Outcome	Control Group (n = 20)	Test Group (n = 20)	p-value
Gender (Female:Male)	15:05	15:05	0.71
Age (years)	48.8 ± 11.1	48.8 ± 10.4	0.99
Income (R$/month)	4,555.00 ± 4,376.67	4,642.11 ± 4,152.02	0.95
Education (years)	11.4 ± 4.1	11.3 ± 3.9	0.94
PASS (%)	23.5 ± 17.0	26.4 ± 20.4	0.63
BoP (%)	15.9 ± 11.6	16.5 ± 12.9	0.70
PD (mm)	2.3 ± 0.23	2.2 ± 0.3	0.15
GR (mm)	1.3 ± 0.6	1.1 ± 0.6	0.25
CAL (mm)	3.6 ± 0.6	3.3 ± 0.7	0.12

Except for gender, values reported are mean ± SD.BoP: bleeding on probing; CAL: clinical attachment level; GR: gingival recession; PASS: Plaque Assessment Scoring System; PD: probing depth.

experimental teeth (Table 1). For all time points examined, there were no differences between groups for PASS, which did not significantly change over time for either group. The mean surgical time was 30.1 ± 7.2 minutes and 29.7 ± 6.4 minutes for TG and CG, respectively (p = 0.84).

Graft related outcomes

Table 2 shows that both surgical techniques promoted a significant gain in KTW ($p < 0.05$). After 12 months, CG experimental teeth showed a KTW increase of 6.1 ± 1.5 mm while TG increased 5.4 ± 1.6 mm, with no significant inter-group differences ($p = 0.16$). Both techniques also resulted in significant KTT increases, when all time points were compared to baseline ($p < 0.05$). After 12 months, the KTT change was 0.6 ± 0.2 mm and 0.5 ± 0.3 mm for CG and TG experimental teeth, respectively ($p = 0.18$). A similar figure was observed for adjacent tooth (Table 2). The KTW and KTT results were similar for adjacent teeth (Table 2). There was no center effect for any of the variables.

No inter-group differences were found for GR ($p > 0.05$). However, both groups showed differences when 12-month results were compared to baseline values. Mean GR reduction at experimental tooth was 0.9 ± 1.2 mm and 1.0 ± 0.7 mm for CG and TG, respectively (inter-group analysis - $p > 0.05$). The GR results for adjacent teeth were similar (Table 2).

Regarding VS, there were no differences between groups at the experimental tooth (CG: 12.8 ± 21.6%, TG: 22.7 ± 22.5%; $p = 0.16$). In the TG group, 20% of cases (n = 4) were classified as needing SMD at the 42-day evaluation.

Patient related outcomes

CG patients experienced significantly more POP at 7 days ($p < 0.001$) (Table 3), for both recipient and donor sites. Moreover, TG patients used less analgesics (5.8 ± 5.0) than CG patients (14.0 ± 10.0) ($p = 0.002$).

There were no differences between groups regarding patient satisfaction with aesthetics, either at 6 ($p = 0.89$) or at 12 months ($p = 0.96$). The mean score was approximately eight for both groups and time-points.

Table 2. Clinical outcomes over time.

Outcome	Group	Baseline	3 months	6 months	12 months	Repeated measures ANOVA effects	Change (12 months - baseline)
KTW (mm), Experimental tooth	Control	0.9 ± 0.7	6.6* ± 1.2	6.8* ± 1.3	7.0* ± 1.3	Time: < 0.001	6.1 ± 1.5
	Test	1.0 ± 0.8	5.8* ± 2.0	6.1* ± 1.6	6.4* ± 1.5	Center: p = 0.94	5.4 ± 1.6
	p-value	0.81	0.13	0.38	0.44	Group: p = 0.40	0.16
KTW (mm), Adjacent tooth	Control	1.8 ± 0.7	7.0* ± 1.1	7.1* ± 1.1	7.4* ± 1.1	Time: < 0.001	5.6 ± 1.4
	Test	1.8 ± 0.9	6.0* ± 1.7	6.5* ± 1.3	6.7* ± 1.4	Center: p = 0.28	4.9 ± 1.5
	p-value	0.70	0.24	0.64	0.57	Group: p = 0.55	0.14
KTT (mm), Experimental tooth	Control	1.0 ± 0.3	1.7* ± 0.37	1.6* ± 0.3	1.5* ± 0.3	Time: < 0.001	0.6 ± 0.2
	Test	1.0 ± 0.3	1.7* ± 0.45	1.5* ± 0.3	1.5* ± 0.3	Center: p = 0.20	0.5 ± 0.3
	p-value	0.34	0.88	0.39	0.18	Group: p = 0.65	0.18
KTT (mm), Adjacent tooth	Control	0.9 ± 0.2	1.7* ± 0.4	1.6* ± 0.3	1.5* ± 0.3	Time: < 0.001	0.6 ± 0.3
	Test	0.9 ± 0.2	1.5* ± 0.2	1.4* ± 0.2	1.4* ± 0.2	Center: p = 0.25	0.5 ± 0.3
	p-value	0.85	0.71	0.26	0.59	Group: p = 0.20	0.79
GR (mm), Experimental tooth	Control	3.4 ± 1.1	2.9* ± 0.9	2.8* ± 0.9	2.5* ± 0.8	Time: < 0.001	-0.9 ± 1.2
	Test	3.3 ± 1.4	2.5* ± 1.2	2.5* ± 1.4	2.3* ± 1.2	Center: p = 0.27	-1.0 ± 0.7
	p-value	0.78	0.60	0.84	0.84	Group: p = 0.49	0.74
GR (mm), Adjacent ltooth	Control	2.7 ± 0.7	2.5 ± 0.8	2.3* ± 0.9	2.2* ± 0.7	Time: < 0.001	-0.5 ± 0.7
	Test	2.6 ± 1.1	1.0* ± 1.1	1.8* ± 0.9	1.8* ± 1.26	Center: p = 0.21	-0.8 ± 0.9
	p-value	0.61	0.19	0.34	0.46	Group: p = 0.18	0.24

* Significant difference vs baseline ($p < 0.05$; Newman-Keuls test), Test group: n = 20; Control group: n = 20; Values reported are mean ± SD. GR: gingival recession; KTT: keratinized tissue thickness; KTW: keratinized tissue width.

Table 3. Postoperative pain (VAS) over time

Outcome	Group	7 days	14 days	21 days	28 days
Recipient site pain	Control	16.15[B] ± 24.65	6.53* ± 12.53	2.60* ± 4.24	0.65* ± 2.01
	Test	4.05[A] ± 6.86	2.16 ± 5.59	1.00 ± 3.21	0.00* ± 0.00
	p-value	< 0.001	0.58	0.87	0.84
Donor site pain	Control	24.30[B] ± 28.25	4.60* ± 8.15	0.80* ± 2.95	0.15* ± 0.67
	Test	9.35[A] ± 15.97	0.95* ± 3.01	0.20* ± 0.89	0.00* ± 0.00
	p-value	< 0.001	0.34	0.87	0.96

*Significant difference from 7 days ($p < 0.05$; Newman-Keuls test) ; Different superscript letters indicate significant difference between groups ($p < 0.05$; Newman-Keuls test) ; Pain at recipient site: Time: $p = 0.008$; Center: $p = 0.72$; Group: $p = 0.028$ (Repeated measures ANOVA); Pain at donor site: Time: $p = 0.003$; Center: $p = 0.57$; Group: $p = 0.047$ (Repeated measures ANOVA); VAS: Visual analog scale.

Discussion

This study showed that at 12 months of follow-up both the conventional and modified FGG techniques were effective in augmenting KT dimensions (width and thickness) at mandibular incisor sites. Postoperative FGG vertical shrinkage at main experimental tooth did not differ between groups and was similar to previously reported values.[14,16,27-32] Surgical time was similar for both techniques. However, the modified technique caused significantly less postoperative pain and lower analgesic intake, compared to the conventional one.

Postoperative pain was less at both donor and recipient sites for patients receiving the modified technique. Since the surgical procedure was identical for the two groups at the donor site, these findings may relate solely to effects of the recipient site differences. It is possible that the protection of the graft, promoted by the flap, resulted in comfort for the subjects during healing. Similarly, the lack of exposed connective tissue (recipient bed) in the TG group may have contributed to the reduced pain experience of these patients. However, based on the nature of the study (parallel group randomized clinical trial), the unlikely possibility exists that there was a serendipitous difference in pain sensitivity between the patients assigned to the two groups; this could account for the significantly greater pain experience of CG patients at the donor site.

Besides the detailed flap differences, the other difference between techniques was suturing. For the conventional technique, a suspensory 'x' suture anchored in periosteum was used to immobilize the graft; this may be technically more demanding for less experienced surgeons. In contrast, the modified technique eliminates this periosteal suture and includes sling sutures to secure the flap over the graft. According to the present data, these differences had no effect on clinical outcomes.

Commonly, root coverage studies restrict their interventions to maxillary Miller class I and II recessions[33] (Cairo RT1[24]). The present investigation included exclusively mandibular incisors with Miller class III recessions[33] (Cairo RT2[24]). Although root coverage was not the primary objective of the performed procedures, both groups showed a significant decrease in GR, by approximately 1 mm at the experimental teeth. Although this was a secondary outcome, it demonstrates that the present approach may be a clinical option for this particular clinical scenario, since there is lack of controlled clinical studies focusing on this region and type of GR. When time points are compared, an incremental GR reduction trend can be detected in both groups over time. These findings may be associated with creeping attachment and suggest that such event may happen even in early phases of the healing process. Further studies are necessary to confirm such data and to elucidate the dynamics of creeping attachment.

After 12 months, all patients showed more than 2 mm of KTW. Currently, 2 mm of KT is considered sufficient for the maintenance of periodontal attachment,[10] so both techniques successfully increased KTW. Considering the present results, in terms of initial FGG dimensions, postoperative FGG shrinkage, and final KTW, it is likely that smaller (narrower)

FGGs would result in KTW within the recommended lower limits. The use of smaller FGGs would result in smaller donor (and recipient) wounds, less pain associated with the procedure, and it could avoid abrupt alveolar mucosa misalignment, a common esthetic problem reported for FGG.[17]

The modified technique presents a potential postoperative complication, which is the occasional flap adherence to FGG, resulting in a superficial soft tissue tunnel, an outcome that can be considered a limitation of this surgical approach. In the present study, 80% of the modified technique cases were free of such a complication. For the 20% of cases that experienced this complication, it was successfully addressed with a simple debridement, a procedure with no postoperative care needs. Based on additional cases from our group, completed independently of this study, it appears that slight technique adjustments, *i.e.*, flap covering only the apical half of the FGG, may avoid keloid, scarring and flap adherence. Such variations have the potential to combine the best of both approaches and should be tested in futures studies.

One limitation of this trial is that it was not possible to prevent performance bias, since it was not feasible to blind surgeons in relation to the surgical technique. Furthermore, in spite of promising short-term results, long-term follow-up is needed to confirm whether the reported positive outcomes are sustained over time and whether the FGG epithelial layer coverage by the flap will not cause complications at a later time.

The present study was conducted as a multicenter trial. The results indicate that there was no center effect for either clinical or patient-reported outcomes. This is attributed to the rigorous and detailed pre-trial calibration of the participating experienced surgeons, the instituted monitoring between centers during the trial, the calibration of the examiners and the extensive patient eligibility criteria. The aforementioned factors contribute to the strengths of this study.

Conclusions

The modified FGG technique was not different than the original technique with regard to the primary outcome (KTW). Both techniques resulted in satisfactory KT augmentation. The potential advantages of the modified technique are reduced postoperative pain and lower analgesic intake.

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