Biologically guided flap stability: the role of flap thickness including periosteum retention on the performance of the coronally advanced flap–A double-blind randomized clinical trial

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Article type : Randomized Clinical Trial

Biologically guided flap stability: the role of flap thickness including periosteum retention on the performance of the coronally advanced flap. A double blind randomized clinical trial.

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Keywords: coronally advanced flap; gingival recession; complete root coverage; flap elevation; flap thickness

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Conflict of interest and source of funding statement

The authors report no conflict of interests related to the study.

ClinicalTrials.gov ID: NCT03417232

Abstract

Aim: to evaluate the possible benefit on wound healing and flap stability of periosteum inclusion, comparing a “split-full-split” thickness flap elevation versus a “split" thickness approach performed during CAF for the treatment of isolated-type gingival recessions in the upper jaw.

Material and Methods: forty patients were randomized, 20 were treated with “split-full-split” (test group) and 20 with a “split” approach (control group). Analyzed parameters at 1 year were: CRC, percentage of Recession Coverage (RC), Keratinized tissue (KT) gain, patient-related outcome measurements.

Results: after 12 months, CRC was 80% in the test group and 35% in the control group. Percentages of RC and KT gain were higher in the test group and a significant association between CRC and the thickness of the flap after elevation was found. Patient-related outcomes measurements were better for the test group.

Conclusions: flap thickness preservation and the presence of the periosteum in part of the flap may play a fundamental role in obtaining CRC.

Clinical Relevance

Scientific rationale: there is a lack of evidence on the influence of including or not the periosteum in the flap during elevation of a coronally advanced flap for obtaining a CRC.

Principal findings: frequency of CRC and percentages of RC showed a superior performance for the “split-full-split” thickness (test) than for the “split” thickness (control) elevation. Moreover, patient-related outcome measurements achieved in the test group were better than the control group.

Practical implications: flap thickness preservation and inclusion of the periosteum in the flap during elevation of a coronally advanced flap may play a role in the achievement of better recession reduction outcomes and patient-related outcomes.

Introduction

Treatment of buccal gingival recession (GR) is the common clinical requirement from patients who are mainly concerned about aesthetics. Noteworthy are also requests linked to root sensitivity, difficulty in oral hygiene procedures, presence of root caries and non-carious cervical lesions (Tonetti & Jepsen, 2014). GR defects, when left untreated, do not improve spontaneously and may progress toward increased recession depth (RD) and clinical attachment loss which increase the patient's aesthetic concern and the clinical discomfort due to augmented dental hypersensitivity (Chambrone & Tatakis, 2016).

Complete root coverage (CRC) can be considered the primary clinical outcome (Chambrone & Tatakis, 2015) and selecting the surgical technique depends mainly on the local anatomical characteristics and on the patient's demands (De Sanctis & Clementini, 2014).

In patients with a residual amount of keratinized tissue apical to the recession defect, the coronal advanced flap (CAF) may be recommended. This surgical technique results in optimal root coverage, good color blending of the treated area with respect to adjacent soft tissues and a complete recovery of the original (pre-surgical) soft tissue marginal morphology (De Sanctis & Zucchelli, 2007). Furthermore, post-operative morbidity is reduced to a single area of surgical intervention and the overall chair time is limited.

When utilizing CAF technique, critical factors in CRC have been described in the literature. Flap positioning coronal to the CEJ (Pini Prato et al., 2005) and a tension-free flap design (Pini Prato et al., 2000) are among the most important ones. Moreover, flap thickness has been shown to influence the clinical outcomes of CAF procedure (Baldi et al., 1999).

Coronally advanced flap has been widely validated by the literature for the treatment of single recession defects (Cairo et al. 2014) and, currently, different flap designs and technical modifications are available to clinicians (Norberg et al., 1926; Bernimoulin et al., 1975; Allen & Miller, 1989; Pini Prato et al., 1992).

De Sanctis and Zucchelli (2007) have introduced the “split–full–split” flap elevation modality. According to the authors, the modulation of flap thickness, produced by the inclusion of periosteum in the central area, increases flap thickness in the portion of the flap residing over the previously exposed avascular root surface. This, in turn, would give better stability to the flap. However, the partial-thickness flap approach used to be commonly performed and taught in the clinical practice and it is validated in the literature (Allen & Miller, 1989, Da Silva et al. 2004).

To date, evidence is still lacking on the influence of including the periosteum in the flap when compared with a split thickness approach in obtaining a CRC.

Thus, the aim of this double blind, controlled and randomized clinical trial was to evaluate the possible benefit on wound healing and flap stability of periosteum inclusion comparing a “split-full-split” flap elevation versus a “split” thickness approach when CAF is performed for the treatment of isolated-type gingival recessions in the upper jaw.

Materials and Methods

Study design

This investigation was a parallel, randomized, single centre clinical trial with blinded outcome assessment on the treatment of single maxillary gingival recession defects according to the CONSORT statement (http://www.consort-statement.org/). The study was registered on ClinicalTrial.org (ID: NCT03417232). Two different treatment modalities were compared: the CAF with a “split-full-split” thickness (SFPT) flap ele-

vation (test group) and the CAF with a partial thickness (PT) flap elevation (control group). The flow chart of the study is presented in **Fig. 1**.

Population

Before any therapy was accomplished, in full accordance with the ethical principles of the Declaration of Helsinki on experimentation involving human subjects, as revised in 2000, the protocol was approved by the University Ethical Board (Ref. CAF0001 23.04.13) at University of Siena, Italy. Patients agreed to participate in the study by signing a written informed consent according to the above-mentioned principles. The participants were selected on a consecutive basis among patients of the Department of Periodontology at the University of Siena, Italy, between April 2013 and April 2015.

Inclusion criteria

In order to be included in the current clinical investigation, patients had to meet the following criteria:

- age >18 years,
- no systemic diseases or pregnancy,
- smoking $\leq$10 cigarettes/day,
- full-mouth plaque score and full-mouth bleeding score $\leq$20%,
- presence of at least one Miller class I isolated recession defect (Miller, 1985) in the upper jaw and at least 2 mm of keratinized tissue apical to the recession,
- recession depth (RD) equal to or greater than 2mm,
- identificable cemento-enamel junction (CEJ),
- vital teeth, free from caries or prosthetic crown,
- no history of periodontal surgery at experimental sites.

Randomization, allocation concealment, and blinding.

A blocked randomization (for gender and smoking status) was performed using a computer software by someone not involved in other aspects of the study. Allocation concealment was performed by opaque sealed envelopes that were opened after designing the flap over the soft tissues. The surgeon was not blind to treatments. Examiners, patients and statisticians were blind to procedures.

Clinical assessment

The following parameters were recorded with a periodontal probe (PCP UNC 15, Hu-Friedy) at baseline and 12 months:

- full-mouth plaque score (FMPS) (O'Leary, 1972), and presence/absence of visible plaque
- full-mouth bleeding score (FMBS) (Muhlemann & Son 1971) and presence/absence of bleeding on probing at study tooth site
- recession depth (RD), measured from the cemento-enamel junction (CEJ) to the most apical extension of the gingival margin.
- probing depth (PD), measured from the gingival margin to the bottom of the gingival sulcus.
- clinical attachment level (CAL), measured from the CEJ to the bottom of the gingival sulcus.
- keratinized tissue height (KTH), measured from the most coronal extension of gingival margin to the mucogingival line.

Other parameters were recorded, as:

- Dentin hypersensitivity (DH), assessed by 10s air spray applied to the exposed buccal cervical area,
- Gingival thickness (GT) at baseline, determined by inserting a needle with a silicon stop, perpendicular to the tissue surface 3 mm apical to the gingival margin. After reaching the hard surface, the silicon stop was slid and placed in contact with the soft tissue (Zucchelli et al. 2010). After removing the needle,

the distance between the tip of our needle and the silicon stop was measured with a caliper accurate to the nearest 0.1 mm.

- Flap thickness (FT), recorded intra surgically after a 3mm elevation apical to the gingival margin, using a Iwansson gauge, modified (without the spring) in order to avoid excessive pressure on the soft tissue (Baldi et al. 1999).

Patient-centred outcomes

A visual analogue scale (VAS) was used to assess:

- postoperative discomfort, bleeding and swelling, at 7 days after surgery (0= no discomfort at all and 10 = extreme discomfort)
- esthetic evaluation, in terms of root coverage and colour match, at 12 months (0= bad aesthetic and 10= good aesthetic)
- satisfaction, in terms of overall satisfaction to the treatment, at 12 months (0= no satisfaction at all and 10= high satisfaction)
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Investigator training

All surgeries were performed by the same operator (MC) and all clinical measurements were performed by two blinded examiners (N.D, C.D.). They were calibrated by measuring twice, 24h apart, the PD and the RD of 3 patients not included in the study. Kappa statistic was used to determine inter and intra-examiner reproducibility.

Pre-treatment: modification of oral hygiene habits

After the screening examination, all subjects received a session of prophylaxis including proper oral hygiene instructions (OHI), scaling and professional tooth cleaning, by means of a rubber cup and a low abrasive polishing paste. In the presence of recession-type defects, a “coronally directed” roll technique was suggested to minimize trauma at the gingival margin. Surgical treatment of recession defects was not performed until all patients displayed an adequate standard of supra-gingival plaque control (FMPS < 20%), as well as low tissue inflammation (FMBS< 20%)

Surgical technique

The design of the flap consisted of two horizontal beveled incisions (3mm in length), mesial and distal to the recession defect, and two slightly oblique beveled incisions. In the test site (SFST) the resulting trapezoidal-shaped flap was elevated with a split–full–split approach in the coronal–apical direction (De Sanctis & Zucchelli, 2007). The surgical papillae comprised between the horizontal incisions and the sulcular area apical to the recession were both elevated split thickness. Conversely, the central portion of the flap apical to the recession was elevated full thickness by the use of a small periostium elevator inserted into the probable sulcus up to exposing 3–4mm of bone apical to the bone dehiscence.

(fig. 2). In the control group (PT) the flap was fully elevated with a split thickness approach, inserting the blade (15c) of the knife into the sulcus and continuing dissection with the blade to the mucogingival line (Allen & Miller, 1989, Da Silva et al. 2004) **(fig. 3)**. In both groups the incision was terminated apically to the mucogingival line by means of a split thickness elevation to free the flap from muscle tension, keeping the blade (15c) parallel to the external mucosal surface. When the margin of the flap reached passively a level coronal to the CEJ of the tooth affected by recession, the coronal mobilization was considered adequate. Only the portion of root surface relative to loss of clinical attachment was mechanically treated utilizing curettes, and the application of EDTA for two minutes followed by a rinse of physiologic solution. The flap was positioned 1mm coronal to the CEJ. The suture of the flap started with two interrupted periosteal sutures performed at the most apical extension of the vertical releasing incisions; afterwards, it proceeded coronally with other interrupted sutures, each of them directed, from the flap to the adjacent buccal soft tissue, in the apical–coronal direction. The last sling suture allowed for the stabilization of the surgical papillae over the inter-dental connective tissue bed and allowed for a precise adaptation of the flap margin over the underlying convexity of the crown.

Post-surgical infection control

Patients were instructed to rinse with chlorhexidine solution (0.12%) twice a day for 1 minute. Fourteen days after surgery, sutures were removed and the patient was prompted to rinse with chlorhexidine for 2 more weeks to maintain plaque control in

the treated area. After this period, patients were again instructed to a mechanical cleaning of the treated region using a post-surgical toothbrush. All patients were re-called for control appointments at 2, 4 and 6 weeks after suture removal and, subsequently, once every 3 months until 1-year follow up.

Sample size determination

The sample dimension was calculated using α= 0.05 and the power (1-β) of 90%0.. The minimum expected effect size was estabilished on a difference of 515%, from 37% (the median of CRC for CAF alone of included studies in the systematic review by Cairo et al. 2014), to 88% (the higher CRC for CAF alone of included studies in the systematic review by Cairo et al. 2014 0). Calculations were performed using Stata 15 IC (Stata corp.). On the basis of these data, the needed number of patients to be enrolled in this study was 20 for the test group and 20 for the control. However, the number of patients was increased of 20% each arm considering the possibility of drop out.

Data analysis

Descriptive statistics were expressed as mean, standard deviation (SD) and confidence of interval at 95% (C.I: 95%). Percentages of RC and the achievement of CRC at 12 months were calculated.

The primary outcome was determined by the number of patients with recession defects that obtained CRC. Secondary outcomes were the percentages of RC, change in RD, KTH and DH, patient's discomfort (VAS discomfort), patient's preference in terms of aesthetic result (VAS esthetic) and patient's satisfaction (VAS satisfaction).

Student's t-test was used to evaluate the differences between groups regarding RD, PD, GT, FT, percentage of RC, KTH, DH, VAS discomfort, VAS aesthetic and VAS satisfaction. Paired t-test was used to evaluate the differences between baseline and 1-year follow-up of RD, PD, KTH, DH. The Pearson's chi-square test was used to compare the two groups regarding CRC. A logistic regression model was fitted to re-

late CRC as dependent variable and intra-operative FT as independent variable ($p < 0.05$).

Results

Study population

A total of 50 patients were included in the study: 3 patients declined to participate and 3 patients didn't meet the inclusion criteria. Forty-four patients completed the study procedures. Since 4 patients dropped out during follow up, 40 patients were finally analyzed (CONSORT flow chart, **fig. 1)**.

During the study period all patients presented a good standard of supra gingival plaque control. Experimental (test and control) sites did not show BOP or visible plaque.

No differences were present between groups regarding patient age (test: 38.4 ± 9 years [C.I 95%: 30.4 - 45.3] ; control: 36.4 ±12 years [C.I 95%: 29.6 - 43.2] ; $p > 0.5$), gender (test: 15 females; control: 14 females; $p = > 0.5$) tooth type distribution (test: 2 incisors, 12 canines, 8 premolars; control: 3 incisors, 10 canines, 9 premolars; $p = > 0.5$) and smoking status (test: 10 smokers; control: 12 smokers; $p = > 0.5$). (**Table 1**)

Clinical parameters

Kappa score used to determine intra- and inter- examiner reproducibility was 0.88 and 0.82 respectively.

The descriptive statistics for the clinical parameters measured at baseline and 1 year after surgery for both groups are shown in **Table 2.**

At baseline, there was no significant difference between both groups regarding any of the clinical parameters. RD was 2.47 ± 0.9 mm (C.I 95%: 2 - 3) for the test group and 2.33 ± 0.9 mm (C.I 95%: 1.9 - 2.8) or the control group (p= > 0.5), and PD was 1.4 ± 0.7 mm (C.I 95%: 1 - 2) for the test group and 1.3 ± 0.8 mm (C.I 95%: 1 - 2) for the control group (p= > 0.5). KTH was 2.5 ± 0.7 mm (C.I 95%: 2 - 1.3) for the test group and 2.6 ± 1 mm. (C.I 95%: 2 - 3.2) for the control group (p= > 0.5).

Gingival tissue thickness at baseline was 0.9 ± 0.2 mm (C.I 95%: 0.8 - 1.1) for the test group and 0.9 ± 0.1 mm (C.I 95%: 0.8 - 1.1) for the control group (p= > 0.5). After elevation, flap thickness was significantly different (p= < 0.01) between the test group (0.93 ± 0.1 mm. [C.I 95%: 0.8 - 1.1]) and the control group (0.46 ± 0.1 mm. [C.I 95%: 0.4 - 0.5]).

After 12 months, PD didn't change in both groups (p= > 0.5) whereas RD significantly decreased for both groups (p < 0.01) compared to baseline measurements. A significant between-groups difference was found at 1 year, with the test group presenting higher RD reduction (p = < 0.5), higher percentages of CRC (80% for test group and 35% for control group, with p= < 0.01) and higher percentages of RC (92,3 ± 16.6 [C.I 95%: 83.1 - 100] for test group and 72,5 ± 22.4 [C.I 95%: 60 - 84.9] for control group, with p= < 0.01). KTH slight decreased in the control group (p= > 0.5) while it slightly increased in the test group (p= 0.5).

Logistic regression analysis showed a significant association between CRC and the thickness of the flap resulted after elevation (p= < 0.01)

Patient-centered outcomes

The descriptive statistics for patient-centered outcome are shown in **Table 3.**

Hypersensitivity was present at baseline in 11/20 (55%) of sites in the test group and 12/20 (60%) of sites in the control group (p= > 0.5) while at 1 year it was present in 0/20 (0%) of sites in the test group and 4/20 (20%) of sites in the control group (p= < 0.5).

VAS discomfort during the first week was 2.3 ± 2.5 (C.I 95%:0.9-3.7) for the test group and 5.5 ± 2.4 (C.I 95%: 3.8-7.3) for the control group, showing a statistically significant difference between groups (p = < 0.01).

VAS aesthetic and satisfaction at 12 months were respectively 8.80 ± 1 (C.I 95%: 8.2-9.3) and 8.47 ± 1.1 (C.I 95%: 8.2-9.3) or the test group and 8.20 ± 1.6 (C.I 95%: 7.8-9.3) and 8.20 ± 1.6 (C.I 95%: 7.8-9) for the control group, with no statistically difference (p= 0.2 for VAS esthetic and p= 0.7 for VAS satisfaction). Considering a range from 5 (neutral) to 10 (very good) of the VAS scale, a significant difference was found in favour of the test group as for VAS satisfaction (p= < 0.5) but not for VAS aesthetic (p= 0.05).

Discussion

The present parallel, double blinded, randomized clinical trial compared clinical and patient-centered outcomes between coronally advanced flaps (CAF) for the treatment of Miller's type I and II gingival recessions. Periosteum retention ("split-full-split" approach, test group) provides superior clinical results in terms of CRC (main outcome variable) and RC; hypersentivity and post-surgical discomfort were also significantly improved.

The main outcome variable of the current investigation was the CRC. The frequency of CRC achieved by the test group was twice as high as that of the control group. Also for root coverage (RC), as a secondary outcome variable, the results obtained show a superior performance for the SFST (test) than for the ST (control).

The marked clinical differences obtained between the two experimental groups seem to confirm the biological rational that we are trying to test, so that the periosteum included within the flap and the use of the elevator in detaching the sulcular area may contribute to a better flap stability over the avascular root surface and a consequent better clinical result.

The surgical technique that detaches the marginal tissue by means of periosteum elevator instead of a surgical blade, may prevent the reduction of the marginal thickness by avoiding involuntary micro wounds of the marginal area and by maintaining the entire structure of the sulcular area. The major thickness of the marginal area can have a role in absorbing or deflecting wound-rupturing forces that otherwise would have been transmitted to the fibrin clot at the root surface - mucogingival flap interface.

From a biologic standpoint, the role played by the periosteum seems to be crucial. Actually, during the very early phases of healing, the stability of a new fragile matrix (blood clot) is challenged by mechanical forces acting on the wound margins (Kon et al., 1969, Wikesjo et al., 1990, Laurens et al., 2006). The split-full-split flap modulation guarantees several biological conditions that may help a new connective tissue formation during these early phases of wound healing. In vivo preclinical studies have shown how the clot stability and its adhesion to the root surface positively influence the formation of a new attachment instead of a long junctional epithelium (Haney et al., 1993, Wikesjo et al., 1991 a, b). In this study the intrinsic stiffness of the periosteum included within the flap have probably maintained the maximum thickness of the most critical area, that is the avascular root surface. Furthermore,

the periosteum, with its high vascularization, provides an important source of cells (fibroblasts and macrophages above all) and growth factors (transforming growth factors beta family). Over the previously denuded root surface, the periosteum indeed can accelerate the phase of new tissue formation, acting as a source of endothelial cells (Potente et al., 2011) and fibroblasts (Griebb et al., 2011); the availability of these cell type in the periodontal wound is crucial to speed up the transition from a catabolic to an anabolic phase and, hence, the maturation/stabilization of the blood clot (Grieb et al 2011).

Our data agree with those published in a recent systematic review in which a range of 34.2 % - 96.6% for RC and 7.7 % - 88% for CRC was reported when a single recession was treated by a CAF (Cairo et al. 2014). Results from meta-analysis showed that CAF plus Connective Tissue Graft (CAF+CTG) or CAF plus Enamel Matrix Derivative (CAF+EMD) was more effective than CAF alone in terms of CRC and RC. Another systematic review (Chambrone & Tatakis, 2015), confirmed the superiority of CAF plus SCTG to provide the best clinical outcomes (CRC, RC) in the treatment of single maxillary recession. Interestingly, the test group in the current investigation has achieved CRC with a frequency quite similar to those found in the systematic reviews by the groups CAF plus SCTG. It is well known that the presence of a connective tissue graft beneath a surgical flap leads to higher percentages of root coverage because it reduces the space for a better blood clot stability and maturation These findings suggest that a modulate flap thickness (“split full split”) may partially mimic the beneficial effects on flap stability that are obtained when a connective tissue graft is added.

According to the modification of the technique, in the test group the soft tissue apical to the root exposure was elevated full thickness by inserting a periosteum elevator in the probable sulcus. On the contrary, in the control group, a blade was used at the buccal aspect of the involved teeth, elevating the flap by a split thickness approach (Allen & Miller 1989, Da Silva et al. 2004). A statistically significative difference regarding the flap thickness in the two groups (0.93 ± 0.1 mm. for test group and 0.46 ± 0.1 mm. for control group) suggests that the “split-full-split” approach is able to preserve entirely the soft tissue thickness of the sulcular area.

Moreover, in this study, linear regression analysis showed a significant association between recession reduction and flap thickness resulted after the elevation. The critical role of soft tissue thickness for successful root coverage with the CAF technique was well reported in the previous literature. Baldi et al. (1999) demonstrated, in 19 patients that flap thickness and recession reduction are directly related, considering that a flap thickness >0.8 mm was associated with the possibility to obtain complete root coverage. The same association was evidenced also in a systematic review investigating flap thickness as a predictor of recession coverage (Hwang & Wang, 2006).

The successful results in terms of root coverage achieved in the test group of the present study were associated with a slight increase in KTH**.** These findings are in agreement with previously published data, describing single recessions treated with a "split-full-split" approach (de Sanctis & Zucchelli, 2007, Del Pizzo et al., 2005, Modica et al., 2000). The control group (PT) conversely, displayed a decrease in the height of keratinized tissue. This clinical behavior, observed when complete split thickness was performed, agrees as well with previous data (Da Silva et al. 2004). Actually, in the latter investigation, 6 months after a complete "split" CAF, a slight loss of KT was observed.

At the best author's knowledge, this is the first investigation that compares in the same population and in a randomized group two different techniques of CAF for the treatment of single recession defects. In a randomized controlled clinical trial, Mazzocco et. al. (2011) investigated the efficacies of a partial- and full- thickness flap reflections, reporting no differences between study groups in terms of mean RC and KT gain after 6 months of healing. However, they treated multiple adjacent recessions by means of CAF with a sub -epithelial connective tissue graft (SCTG).

The Consensus Report of the Group 2 of the 10th Workshop on Periodontology (Tonetti & Jepsen, 2014) declared that patient-reported outcomes may represent the "true endpoints" of the mucogingival procedure, which capture patients' perceptions of the therapy and complement conventional clinical outcomes. In this clinical trial, patient-centered outcomes were assessed by means of a VAS scale after 7 days (discomfort) and after 1 year (aesthetic and satisfaction). Moreover, the presence or absence of hypersensitivity was assessed.

Root sensitivity at baseline was detected in more than half of the patient population (test and control): the prevalence of this subjective symptom is consistent with that observed in other clinical trials (Santamaria et al. 2017, Pini Prato et al. 2005). After 1 year, root sensitivity was not detectable in the test group but it is still present, albeit in a small percentage of individuals, in the control group. This finding can be related with the greater surface of exposed root still present in the control group at the end of the experimental period and by the lower number of cases in which a CRC was obtained.

The discomfort perceived by individuals part of the control group after the first week of healing was twice as intense as that perceived by the test group. This interesting feature can be partially explained by the greater amount of blood clot produced by the more extensive partial thickness performed in the control group and its consequent greater difficulty to be reabsorbed in the very first phase of healing (first week).

After 12 months VAS aesthetic and satisfaction were respectively 8.80 ± 1 and 8.47 ± 1.1 for the test group and 8.20 ± 1.6 and 8.20 ± 1.6 for the control group, confirming that clinical improvement in RC and the achievement of a CRC is important for the patient's perspective. Considering a range from 5 (neutral) to 10 (very good) of the VAS scale, a significant difference was found in favour of the test group for VAS satisfaction, probably due to the presence in the control group of a higher percentages of root sensitivity.

Conclusions

Within the limits of this study, the following conclusion can be drawn:

1) Thickness modulation of the split-full-split approach preserves soft tissue thickness of the flap at the maximum extent in the portion that will cover the denuded root.

2) Flap thickness preservation and the presence of the periosteum in part of the flap may play a role in achieving better recession reduction outcomes (higher percentages of RC and CRC) at 1 year, with better patient's centered outcomes (higher hypersensitivity reduction at 1 year and lower VAS discomfort at 7 days)).

3) The successful results in terms of root coverage achieved in the present study were not associated with a clinically significant increase in KTH at 1 year.

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Figure legend.

Figure 1. CONSORT flow chart of the study

Figure 2. Split–full–split approach (test group) for the treatment of a localized gingival recession.

Figure 3. Split approach (control group) for the treatment of a localized gingival recession.

Table 1. Study Population

	"split full split" (N=22)	**"split" (N=22)**
AGE	38.4 ± 9 years (30.4 - 45.3)	36.4 ±12.2 years (29.6 - 43.2)
GENDER	15 females 7 males	14 females 8 males
TOOTH TYPE	2 incisors 12 canines 8 premolars	3 incisors 10 canines 9 premolars
SMOKERS	10	12

(Confidence Interval 95%)

Table 2. Clinical parameters

	"split full split" (N=20)	**"split" (N=20)**
RD (mm)		
baseline	2.47 ± 0.9 (2-3)	2.33 ± 0.9 (1.9-2.8)
12 months	0.23 ± 0.5* # (0-0.5)	0.76 ± 0.7 * (0.3-1.2)
PD (mm)		
baseline	1.4 ± 0.7 (1-2)	1.3 ± 0.8 (1-2)
12 months	1.3 ± 0.8 (1-2)	1.2 ± 0.4 (1-2)
KT (mm)		
baseline	2.5 ± 0.7 (2.1-3)	2.6 ± 1 (2-3.2)
12 months	2.7 ± 0,8 (1.8-2.8)	2 ± 0.8 * (1.6-2.4)
GT (mm)		
presurgical	0.9 ± 0.2 (0.8-1.1)	0.9 ± 0.1 (0.8-1.1)
FT (mm)		
intrasurgical	0.93 ± 0.1 # (0.8-1.1)	0.46 ± 0.1 (0.4-0.5)
RC (%)		
12 months	92,3 ± 16.6 # (83.1-100)	72,5 ± 22.4 (60-84.9)

CRC (%)		
12 months	80% (16/20) #	35% (7/20)

* statistically significant difference within 2 groups

statistically significant difference between 2 groups

(Confidence Interval 95%)

Table 3. Patient-centered outcomes

	"split full split" **(N=20)**	**"split"** **(N=20)**
HYPERSENSIVITY		
baseline	60% (12/20)	55% (11/20)
12 months	0% (0/20) * #	20% (4/20) *
VAS DISCOMFORT		
7 days	2.3 ± 2.5 # (0.9-3.7)	5.5 ± 2.4 (3.8-7.3)
VAS SATISFACTION		
12 months	8.47 ± 1.1 § (7.8-9)	8.20 ± 1.6 (7.8-9.3)
VAS AESTHETIC		
12 months	8.80 ± 1 (8.2-9.3)	8.20 ± 1.6 (7.3-9)

* statistically significant difference within 2 groups

statistically significant difference between 2 groups

§ statistically significant difference when VAS range was considered from 5 (neutral) to 10 (very good)

(Confidence Interval 95%)

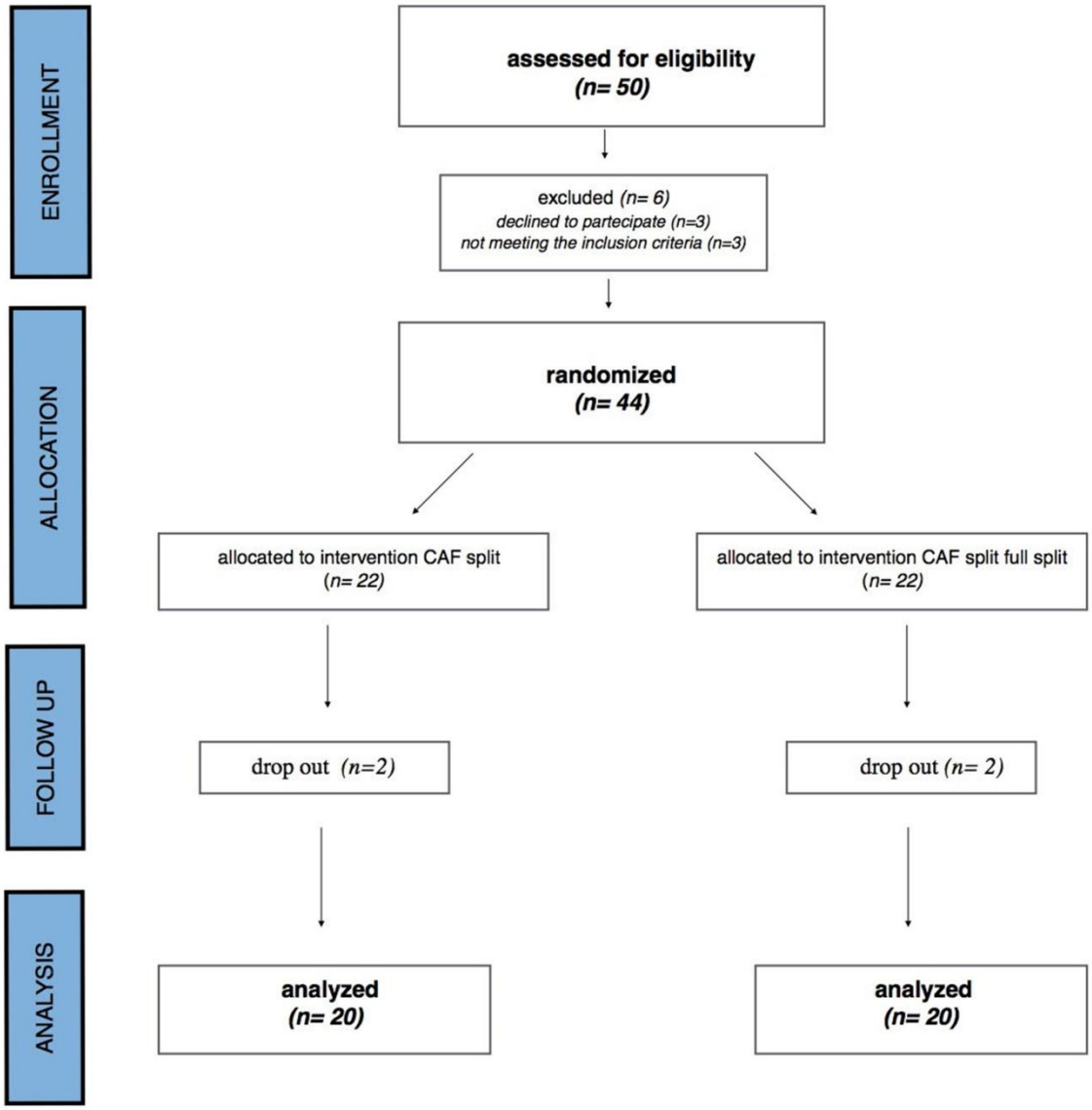

Fig. 1. Flow chart of the study