ISSN: 0975-833X

Available online at http://www.journalcra.com

International Journal of Current Research
Vol. 8, Issue, 04, pp. 29656-29661, April, 2016

INTERNATIONAL JOURNAL OF CURRENT RESEARCH

RESEARCH ARTICLE

COMPARISON OF SUBEPITHELIAL CONNECTIVE TISSUE GRAFTS AND CORONALLY ADVANCED FLAPS IN THE TREATMENT OF SINGLE GINGIVAL RECESSIONS; A RANDOMIZED, DOUBLE-BLIND, CLINICAL TRIAL

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ARTICLE INFO

Article History:
Received 20th January, 2016
Received in revised form
10th February, 2016
Accepted 04th March, 2016
Published online 26th April, 2016

Key words:

Gingival recession,
Miller's class I and class II,
Connective tissue graft,
Clinical trial,
Periodontal surgery,
Root coverage.

ABSTRACT

Aims: This parallel-group, multi-centre, double-blind, randomized-controlled clinical trial was undertaken to compare the clinical outcomes of coronally advanced flap (CAF) alone or in combination with a connective tissue graft (CAF+CTG) in single Miller Class I and II gingival recessions.

Material and Methods: 80 patients were enrolled with one recession each. Coronally advanced flap (CAF) alone surgery was performed in 30 patients; 30 sites randomly received a graft under the CAF. Measurements were taken by blind and calibrated examiners. Outcome measures included recession reduction, complete root coverage (CRC) and side effects.

Results: No differences were noted in the intra-operative and post-operative patient related variables between the two groups. Surgical time was significantly shorter in the CAF group. Recession reduction was not statistically different between the two groups; even though test group showed a tendency towards improved outcomes in sites treated with CAF+CTG (adjusted difference 0.33mm. statistically Significant results of PD, KT and CAL were observed after CAF+CTG ($\leq p = 0.0033$).

Conclusion: Both treatments were effective in providing a significant reduction of the baseline recession and with only limited intra-operative and post-operative morbidity and side effects. Adjunctive application of a CTG under a CAF increased the probability of achieving decrease PD, increase KT and CAL Miller Class I and II defects.

Conflict of interest: No conflict of interest declared by any of the Authors.

Citation: Dr. Muzafar Ahmad Bhat, Dr. Khan Rafiya, N., Dr. Suhail Majid Jan, Dr. Mufeed Ahmad Bhat, Dr. Amir Beig and Dr. Roobal behal, 2016. "Comparison of subepithelial connective tissue grafts and Coronally advanced flaps in the treatment of single gingival recessions; a randomized, double-blind, clinical trial", *International Journal of Current Research*, 8, (04), 29656-29661.

INTRODUCTION

Gingival recession is defined as an apical displacement of soft tissues related to the Cemento-Enamel Junction (CEJ) (Wennstro, 1996). Which can result in unfavorable esthetics, (Albandar and Kingman, 1999) increased root caries susceptibility, (Lawrence *et al*., 1995) and dentin hypersensitivity. (Al-Wahadni and Linden, 2002) Gingival recession affects from 22.5% to 73.1% of individuals. (Albandar and Kingman, 1999; Susin *et al*., 2004; van Palenstein Helderman *et al*., 1998) The possible pathogenesis of gingival recession is related to tissue inflammation produced by biofilm accumulation or traumatic brushing. (Baker and Seymour, 1976) Several surgical techniques have been described to address isolated gingival recession, showing a high predictability in terms of root coverage (Wennstro, 1996; Zucchelli *et al*., 1998), like the free gingival graft (Sullivan and Atkins, 1968), the coronally advanced flap (Allen and Miller, 1989), the CAF with a subepithelial or connective tissue graft (Langer and Langer, 1985), and various regenerative procedures such as the use of non-resorbable barriers (Pini Prato *et al*., 1992), bio-resorbable barriers (Roccuzzo *et al*., 1996), enamel matrix derivative (Rasperini *et al*., 2000), or the application of a platelet-rich gel (Keceli *et al*., 2008) in combination with CAF. Although all these techniques have shown a consistent potential for root coverage but bilaminar techniques (CAF+CTG) has showed a greater recession reduction and a larger amount of roots covered completely. The coronally advanced flap is one of the most effective techniques for the treatment of Miller Class I and II recessions, (Allen and Miller, 1989; Harris and Harris, 1994; Bernimoulin *et al*., 1975; Pini-Prato *et al*., 1999; Trombelli *et al*., 1997) since it leads to excellent esthetic results, and is

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technically simple to perform, and can be used for the treatment of multiple adjacent recessions. (Berlucchi *et al*., 2005) The CAF and the bilaminar techniques are actually perceived as the most reliable procedures. A direct comparison between CAF and CAF+CTG has been performed in this study demonstrated a significant reduction of recession depth, pocket depth, and clinical attachment level both at baseline, 3month and at 6 months in both groups. The aim of this randomized-controlled clinical trial was to compare the root coverage of the CAF alone with the CAF+CTG in the treatment of single Miller Class I and II gingival recessions.

MATERIALS AND METHODS

Study population and design

This was a parallel-group, randomized, double-blind, clinical trial on treatment of gingival recessions (Fig. 1). Two different modalities for root coverage were compared: the CAF and the CAF with a CTG (CAF+CTG, bilaminar technique). Two parallel groups were selected to participate in this study. 60 patients were enrolled for the study and were equally distributed in control and test group in a period of time between May 2013 and December 2014. Each patient (experimental unit) contributed with a recession. In case of patients presenting with multiple recessions, the deepest one was selected; in case of two or more recessions with the same depth, the selection was performed by tossing a coin. Every patient in control group was treated with CAF alone and in test group patients were treated with CAF plus CTG. Early healing events were evaluated at weeks 1, 2, 3, and 4. Clinical outcomes were evaluated at 3 and 6 months. All patients received initial therapy consisting of oral hygiene instructions, scaling and root planning. Six weeks later, a reevaluation was performed and all the patients recorded an O'Leary index ≤10% (Leary *et al*., 1972). The patients were provided with comprehensive information concerning the nature and potential risks of surgery involving autogenous gingival grafting with CAF for root coverage. The patients provided consent prior to the initial therapy and were treated between May 2013 and December 2014. The study was conducted in Govt. Dental College and hospital Srinagar.

Measurements

The following biometric clinical parameters were evaluated in millimeters mid-facially: recession level (RL), probing depth (PD), clinical attachment level (CAL) and width of the keratinized tissue (KT) using a Marquis periodontal probe (Hu-Friedy). All the clinical measurements were done by the same calibrated blinded investigator and were rounded down to the nearest millimeter at baseline (immediately before surgery) 3 and 6 months after the surgical intervention in both treatment groups. Patients were blinded to the test and control sites. Results are presented at the subject level.

Surgical procedure

Preoperative intra-oral antisepsis was accomplished using 0.12% chlorhexidine digluconate solution (Periogard) rinsed for 1 min. Before the surgery, the root surface was gently scaled and planed with Gracey curettes (Hu-Friedy), which contributed to reduce buccal prominence. Then, the root surfaces were conditioned with EDTA gel (pH 6.7) for 2 min to remove the smear layer. The exposed root surface was rinsed abundantly with sterile saline solution to remove all EDTA residues. After local anesthesia with lidocaine HCl (2%) containing 1:100,000 epinephrine was achieved. The coronally advanced flap surgery was conducted according to the technique described by Allen and Miller (1989) (single recession-type defects). In test groups the patients were treated by CAF and CTG. Two oblique, divergent beveled incisions were performed at the mesial and distal line angles of the tooth (single recession-type defects). After intrasulcular incisions, crossed submarginal interproximal incisions created the interdental surgical papillae.

The flap was raised using a split-full split approach in the coronal-apical direction: from the oblique interdental incisions, a split-thickness flap was raised to create surgical papillae, the gingival tissue apical to the root recessions was raised in a full thickness manner to expose about 3.0 mm of bone, and a split-thickness flap was elevated at the most apical apical portion of the flap to allow flap coronal movement without tension. Root surfaces previously exposed at the oral cavity were thoroughly mechanically decontaminated using Gracey instruments. The remaining tissue of the anatomic interdental papilla was deepithelialized, creating a connective bed for flap coronal advancement. The connective tissue graft in proper dimensions to cover the root surfaces and surrounding bone was harvested from the palate in the premolar area (Bruno, 1994) and trimmed to remove visible epithelium. The donor site was covered by soframycin gel held by Howles appliance. The graft was placed at the CEJ level covering the entire defect and interdental connective tissue bed and held in place using sling sutures. The flaps were positioned at the level of, or slightly coronal to, the CEJ, in such a way that the created surgical papillae were moved coronally and laterally over the anatomical papilla. Sling sutures were used to stabilize the flap. However in case of control group only coronally advanced flap procedure were done described by Allen and Miller.

Statistical analysis

60 subjects were enrolled in a clinical trial having gingival recession defects in which coronally advanced flap (control group) were compared with a combination of CAF and CTG (test group). Two groups were selected for this study, one group were randomized to test and the other group to control. The clinical variable changes were compared at baseline, 3 and 6 months after surgery. Descriptive statistics were expressed as mean ± standard deviation (S.D.). A *t*-test analysis was performed with the subject as the analysis unit. *P* values <0.05 were regarded as statistically significant.

RESULTS

60 patients, 57 males and 3 females, aged 25 to 59years (mean 37.8 ± 8.4), contributed at least one class I r class II gingival recession defects in canines and/or premolars. In the test group, the recession defects were treated with CAF+CTG and in the control just CAF was used, in two parallel designs.

Table 1. Baseline defect-related charecteristics

	CAF (η =30) mean±SD	CAF+CTG (η =30) mean±SD
Recession level	2.4 ± 0.7	2.7 ± 0.7
PD	1.2 ± 0.4	1.2 ± 0.4
CAL	3.2 ± 1.3	3.8 ± 0.8
KT	3.2 ± 1.3	2.7 ± 1.2

Table 2. Statistics of variables recorded 3 and 6 months after surgery in mm (mean±SD)

	CAF (η =30) mean±SD	CAF+CTG (η=30) mean±SD	CAF (η =30) mean±SD	CAF+CTG (η=30) mean±SD
Recession level	0.8 ± 0.8	0.4 ± 0.7	0.8 ± 0.8	0.6 ± 0.9
PD	1.2 ± 0.6	1.1 ± 0.4	1.4 ± 0.6	1.4 ± 0.5
CAL	2.1 ± 1.2	1.6 ± 0.8	2.3 ± 1.2	2.0 ± 1.0
KT	2.9 ± 0.9	3.2 ± 0.9	3.0 ± 0.8	3.3 ± 0.9

Test group (patients in which CAF+CTG procedure is done)

PRE-OPERATIVE VIEW SHOWING CLASS I MILLER RECESSION ON IST PREMOLAR

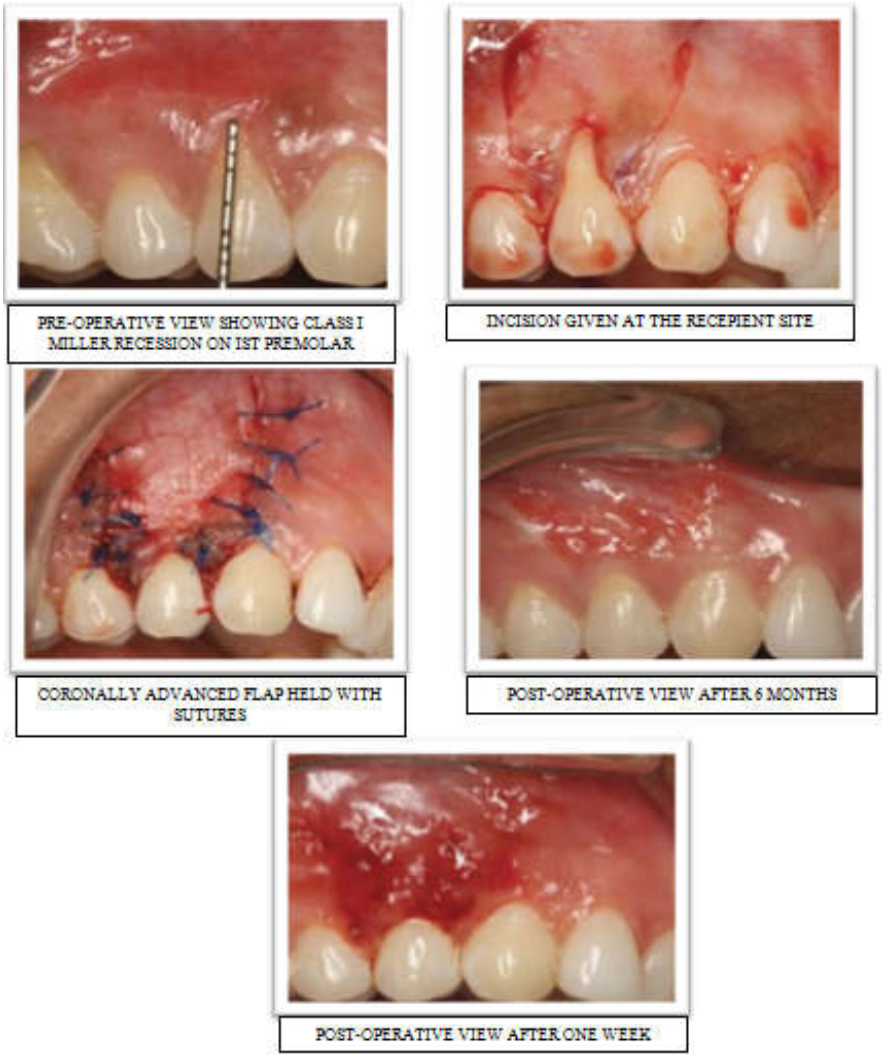
INCISION GIVEN AT THE RECEPIENT SITE

FLAP REFLECTION DONE

POST-OPERATIVE VIEW AFTER 6 MONTHS

GRAFT PLACED AT THE RECEPIENT SITE

Control group (patients in which CAF procedure is done)



Gingival bleeding index and plaque index were kept below 20% throughout the observation period. At the baseline, no statistically significant differences were found between the two groups in any of the parameters evaluated. Both groups showed a statistically significant result in RL, PD, KT and CAL 3 and 6 months postoperatively, compared to the baseline (intergroup comparison). The test group showed statistically better results than the control group for RL (0.8 ± 0.8 mm and 0.8 ± 0.7 mm, respectively) and CAL changes (2.1 ± 1.2 mm and 1.6 ± 0.8 mm, respectively) at 3 months and for RL (0.8 ± 0.8 mm and 0.6 ± 0.9 mm, respectively), PD (1.6 ± 0.6 mm and 1.4 ± 0.5 mm, respectively), KT (3.0±0.8 and 3.3±0.9) and CAL (2.3 ± 1.2 mm and 2.0 ± 1.0 mm, respectively) at 6months (intergroup comparison). The mean root coverage in percentage at 6 months postoperatively was 70% in the test group and 54.8% in the control group. There was no statistically significant difference in reducing recession depth between the groups for both evaluation periods, though the 0.33 recession reduction was observed in bilaminar technique, and for PD changes in the 6-month postoperative evaluation. Table 1 presents descriptive statistics for the clinical parameters at baseline, and Table 2 presents descriptive statistics after 3months and after 6 months, for both groups.

DISCUSSION

The present randomized clinical trial was designed to test the added clinical benefit and the potential additional adverse events of the placement of a CTG under a CAF in the treatment of Miller Class I and II single gingival recessions Both the test and the control procedures were effective in reducing the recession depth; 0.33mm greater recession reduction was observed in the cases treated with the bilaminar technique (Table 2). These data confirm the outcomes of a previous small sample controlled study (Da Silva *et al*., 2004) in which sites treated with CAF+CTG resulted in improved clinical outcomes with respect to CAF alone, but the difference did not reach statistical significance. In the present clinical trial, however, the adjunctive application of a CTG under a CAF increased the probability of achieving CRC in Miller Class I and II defects. The sites treated with a combination of CAF plus a graft resulted in a significantly higher number of recessions completely covered (70%) with respect to sites treated with CAF alone (54.8%, Table 2). In this study, a site was declared ‘‘completely covered’’ when the CEJ or the coronal part of a step was not visible, so shallower baseline recessions had a higher probability of being completely covered. The CAFs with

or without the use of a graft are technique-sensitive procedures that require a specific and refined training and a high level of skills to be properly applied. Another relevant, although expected, difference between the two tested techniques was the change in KT between baseline and 6 months. Sites treated with the bilaminar technique resulted on average in a KT increase at 6 months, while the ones treated with CAF resulted in a slight loss (Table 2) Comparing the two procedures, the CAF+CTG provided a significant increase in KT on top of CAF alone (Table 2). This event might be explained, at least in part, by difference in the size of the CTG and in the accuracy of the surgical performances. The differences noted between the two experimental procedures can be further explored and explained by analyzing the soft tissue changes during the early healing phase. Both procedures were performed with a clear goal in mind: provide a complete coverage of the treated roots. To reach this objective, the best of clinical skill was applied in trying to obtain a tension-free pedicle flap, to position the flap margin corona to the CEJ, and to provide flap stability with the suturing technique (Pini Prato *et al*., 2005; Zucchelli *et al*., 2003). In spite of these efforts, the CEJ was visible in five CAF- and in three CAF+CTG-treated sites at the end of suture positioning. At week 1, only two CAF- and one CAF+CTG-treated sites revealed an exposed CEJ. The reduced number of sites with a visible CEJ could easily be explained by the slight inflammation (44% CAF and 43% CAF+CTG) and swelling (28% CAF and 36% CAF+CTG) noted at this time point of the healing period. Both inflammation and swelling rapidly dropped down to half of the positive cases at week 2 and further down at weeks 3 and 4. Along with the resolution of the post-operative inflammatory events, an increased number of sites with a visible CEJ were recorded at weeks 2, 3, and 4. At the 3- and 6-month examination visits, an exposed CEJ was recorded in 25 CAF- and 17 CAF+CTG-treated sites and 27 CAF- and 17 CAF+CTG-treated sites, respectively. The increasing exposure over time following both procedures could be explained by the tendency of the coronally advanced soft tissue to experience some contraction in the early healing phase: this is in agreement with previous similar observations (Pini Prato *et al*., 2005). Interestingly, there is a difference between the two procedures in favour of the bilaminar technique, where a CTG was positioned to increase the thickness of the covering soft tissue. The presence of a graft under the flap is associated with a reduced soft tissue contraction, resulting in a significantly greater amount of sites completely covered at 6 months. The overall surgical chair-time was significantly shorter for CAF (about 17 min. on average, Table 3). This is easily explained by the additional time required to harvest, position, and suture the CTG in the CAF+CTG. The prolongation of the chair-time could potentially influence patient perception of the procedure's hardship and some of the post-operative clinical parameters, like inflammation and swelling.

However, these potential correlations were not significant in the present study. The post-operative regimen adopted in this trial was designed to reduce direct trauma or any mechanical negative influence on the treated area. Three weeks after surgery, the patients were allowed to resume regular mechanical tooth cleaning of the treated areas using a toothbrush with the appropriate technique.

Acknowledgements

This research has been supported by Govt. Dental College and Hospital Srinagar. The authors would like to thank Dr. Suhail Majid for his support during the study and help in analysis.

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