Evaluation of efficacy of a novel resorbable collagen membrane for root coverage of Miller’s Class I and Class II recession in the maxillary anteriors and premolars

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Abstract:
Background: There are several surgical techniques in literature that have been used to perform root coverage (RC). Currently, the use of a resorbable collagen membrane (RCM) as a guided tissue regenerative material is one of the highly sought treatment modalities. The present study aimed at evaluating the clinical outcome of RC in the treatment of Miller’s Class I and II recession defects in maxillary anteriors and premolars by coronally advanced flap (CAF) with and without RCM. Materials and Methods: This split-mouth study (bilateral buccal recession defects) was randomized to include 15 test (CAF + membrane) and 15 control (CAF alone) sites. Clinical parameters included gingival recession depth (RD), probing pocket depth (PPD), clinical attachment level (CAL), and keratinized tissue height (KTH) measured at baseline and 9 months postoperatively. Results: Both test and control groups showed statistically significant ($P < 0.05$) reductions in RD (1.54 ± 0.46 mm and 1.60 ± 0.07 mm), PPD (0.53 ± 0.15 mm and 0.94 ± 0.10 mm), increase in KTH (0.67 ± 0.90 mm and 0.73 ± 0.14 mm) and CAL (1.94 ± 0.27 mm and 2.60 ± 0.19 mm) when comparing the 9-month data from baseline. The present study showed that mean improvement in RD was 1.60 ± 0.507 and 1.53 ± 0.64 mm in both test and control groups, respectively. Mean percent RC was 58.33% ±12.19% and 56.22% ±10.22% for test and control groups, respectively. However, there were no statistically significant differences between groups for RD, PPD, KTH, and CAL.

Conclusion: The results of this study suggest that both the groups CAF (control) and CAF and RCM (test) could be successfully used to treat Miller’s Class I and II gingival recession defects and also demonstrated an overall significant improvement in all the assessed clinical parameters. However, there was a greater reduction of gingival RD with the use of RCM when compared with the group of CAF alone.

Key words: Barrier membrane, coronally advanced flap, gingival recession/therapy, guided tissue regeneration, resorbable collagen membrane

INTRODUCTION

The term gingival recession is denoted as the exposure of the root surface by the apical displacement of the gingival margin in relation to the cementoenamel junction (CEJ).\[1\] Even after meticulous maintenance by the patient, if the gingival recessions were not treated at the appropriate time, the prognosis seemed to be on the negative side, but at the same time, when treated by performing perio-plastic procedures, the prognosis seemed to improve.\[2\] The possible consequences of gingival recession are compromised esthetics, dentinal hypersensitivity, cervical abrasions, plaque retention, and high incidence of root caries. Usually, patients seek corrective treatment for root hypersensitivity and esthetic problems.

A root coverage (RC) that is predictable can be seen by several perio-plastic procedures, namely, the free gingival graft technique, pedicle flaps, coronally advanced flap (CAF) technique, and subepithelial connective tissue technique. However, in spite of achieving predictable RC by these procedures, there was formation of a long junctional epithelium during healing. The other

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limitations associated with these procedures are discomfort to the patient, it takes a long duration of time, another surgical site, inadequate supply of donor tissue, and bleeding after surgery.[9]

Guided tissue regeneration (GTR) that is one of the commonly sought treatment modalities aims at guiding the proliferation of the epithelial cells and at the same time makes sure that they do not proliferate into the areas that is desirous of achieving periodontal regeneration.[10] As per Leknes et al., connective tissue repair to the exposed root surface is not achieved by GTR as RC procedure provides only periodontal regeneration.[9] Collagen is semipermeable, allowing nutrient passage and gas exchange. Collagen tissue due to its property of semipermeability enables the passage of nutrients and exchange of gases and aids in the augmentation of the entire tissue volume as it gets absorbed naturally and thereby getting replaced by host tissue.[9]

The present study aimed at evaluating the clinical outcome of RC in the treatment of Miller’s Class I or II recession defects in maxillary anteriors and premolars CAF with and without resorbable collagen membrane (Novabone RCM).[6]

MATERIALS AND METHODS

A total of 15 pairs of bilateral buccal recession defects from 15 patients with bilateral gingival recession defects and in good general health were recruited for the study. The inclusion criteria included age group of 18-45 years (both genders), presence of bilateral gingival recession classified as Miller’s Class I or II recession defects in upper anteriors and premolars, ability to maintain good oral hygiene, patients willing to comply with all the study-related procedures, and those available for follow-up. Patients were excluded from the study for the following reasons: History of prolonged use of antibiotics, periodontal therapy in the preceding 6 months, pregnant and lactating women, history of tobacco use in any form, history of systemic diseases, unwilling patients, gingival recession associated with severe cervical abrasion/cervical caries, and faulty toothbrushing technique.

Clinical measurement

A detailed clinical examination, case history, and informed consent were obtained from all the study participants along with complete hemogram. Acrylic stents were fabricated for the selected sites. A deepest line of recession was analyzed, and a groove was placed in the stent in the line of recession to have a constant reference for standardized measurements at baseline and recall appointments. The following clinical parameters were at 9 months postsurgery from baseline.

- Recession depth (RD) was recorded to the most apical extension of gingival margin from the CEJ
- Probing pocket depth (PPD) was recorded to the base of gingival sulcus from the crest of gingival margin
- The following formula was used to calculate the clinical attachment level (CAL): \( CAL = RD + PPD \)
- Keratinized tissue height (KTH) was measured from the gingival margin to the mucogingival junction
- At 9-month posttreatment, the following formula was used to calculate the RC percentage and improvement in RD:

\[
\text{Percent of root coverage} = \left( \frac{X}{\text{Baseline Recession depth}} \right) \times 100
\]

Presurgical evaluation

A total of 15 pairs of Miller’s Class I or II gingival recession defects in 15 patients were treated with Phase I therapy. Both the groups, namely the test and the control groups, were randomized using lottery method in each patient. Surgery on the second site (e.g., control site) was done 15 days after the suture removal on the test site or vice versa. As per the design of this study, the control sites were treated using CAF alone procedure and the test sites were treated by using CAF + Novabone RCM[6] (bovine Type I collagen membrane).

In both test and control sites, thorough root planning and smoothing of cervical abrasion (if present) in each site were done and it is followed by root conditioning with tetracycline for 1 min.

Surgical protocol

Under local anesthesia, an intrasulcular incision was made with a 15C surgical blade on the buccal side of the involved tooth that extended to dissect the mesiobuccal aspect and distobuccal aspect of the adjacent papillae, horizontally, leaving the gingival margin of the adjacent teeth intact [Figures 2a and 3a]. From the mesial and distal ends of the horizontal incision, two releasing incisions were made obliquely. Using a Molt’s periosteal elevator, a split-full-split-thickness flap was raised [Figures 2b and 3b]. To facilitate the release residual muscle tension and the passive coronal displacement of the flap, a mesiodistal and apical dissection parallel to the vestibular lining mucosa was performed. De-epithelialization of the papillae adjacent to the involved tooth was done. The previous unexposed root surface was planned thoroughly to the marginal bony crest and irrigated thoroughly with normal saline. For control site, the flap was coronally advanced without tension and suturing was done using polyvicryl 4-0 resorbable suture [Figure 2c].

For the test site, before suturing, the collagen membrane was trimmed with a curved cut in the area of the CEJ and was placed over the root or bone, coronal to the CEJ, extending at least to a distance of 2-3 mm beyond the bony margin [Figures 3c]. The membrane [figure 3f] was placed securely in position with a resorbable suture, the flap was passively repositioned coronally over the root or bone, coronal to the CEJ, extending at least to a distance of 2-3 mm beyond the bony margin [Figures 3c]. The membrane [figure 3f] was placed securely in position with a resorbable suture, the flap was passively repositioned coronally with sling suture, and the knot was tied securely. To close the wound of the releasing incisions beyond the mucogingival junction, additional lateral sutures were placed [Figure 3d]. Periodontal dressings were given in both sites.

Postsurgical protocol

At 14 days postoperatively, removal of sutures and periodontal dressing were done. Recall for patients was scheduled for further routine checkup which was kept at 1 and 2 weeks, 1, 3, 6, and 9 months postoperatively. All the postoperative clinical measurements were done at 9 months postsurgery [Figures 2d and 3e for control and test groups, respectively].

RESULTS

The surgical procedures were uneventful, and all patients experienced no complications postoperatively, and complied with the study protocol.
Recession depth
At baseline, the mean RD for the control group was 2.67 ± 0.816, which was reduced to 1.13 ± 0.352 at 9 months with respect to baseline, showing reduction of 1.54 ± 0.46 mm that was statistically significant ($P < 0.0001$) [Table 1 and Figure 1a]. The mean RD for the test group at baseline was 2.73 ± 0.594, which was reduced to 1.13 ± 0.516 with respect to baseline, showing reduction of 1.60 ± 0.07 mm that was statistically significant ($P < 0.0001$) [Table 1 and Figure 1a]. The difference in the mean RD with the test and control groups was 0.06 ± 0.26 which was not statistically significant ($P > 0.05$) [Table 2 and Figure 1a].

Probing pocket depth
At baseline, the mean probing depth for the control group was 1.13 ± 0.35, which was reduced to 0.60 ± 0.50 at 9 months with respect to baseline, showing reduction of 0.53 ± 0.15 mm which was statistically significant ($P < 0.0001$) [Table 1 and Figure 1]. For test group at the baseline, the mean probing depth was 1.07 ± 0.25, which was reduced to 0.13 ± 0.35 at 9 months with respect to baseline, showing reduction of 0.94 ± 0.10 mm which was statistically significant ($P < 0.0001$) [Table 1 and Figure 1b].

The difference in the mean probing depth between the test and control groups was 0.41 ± 0.59 which was statistically significant ($P < 0.01$) [Table 2 and Figure 1b].

Keratinized tissue height
At baseline, the mean KTH for the control group was 3.33 ± 1.23 which was reduced to 4 ± 1.13 with respect to baseline, showing a gain of 0.67 ± 0.90 mm that was statistically significant ($P < 0.005$) [Table 1 and Figure 1c]. For test group at the baseline, the mean KTH was 3.27 ± 1.22, which was reduced to 4 ± 1.36 at 9 months with respect to baseline, showing a gain of 0.73 ± 0.14 mm that was statistically significant ($P < 0.001$) [Table 1 and Figure 1c].

The difference in the mean KTH between the groups was 0.06 ± 0.76 which was not statistically significant ($P > 0.05$) [Table 2 and Figure 1].

Clinical attachment level
At baseline, the mean CAL for the control group was 3.67 ± 0.97, which was reduced to 1.73 ± 0.70 with respect to baseline, showing an improvement of 1.94 ± 0.77 mm that was statistically significant ($P < 0.001$) [Table 1 and Figure 1d]. For test group at the baseline, the mean CAL was 3.62 ± 0.98, which was reduced to 1.27 ± 0.83 at 9 months with respect to baseline, showing an improvement of 2.35 ± 0.36 mm that was statistically significant ($P < 0.001$) [Table 1 and Figure 1d].

The difference in the mean CAL between the groups was 0.40 ± 0.57 which was not statistically significant ($P > 0.05$) [Table 2 and Figure 1d].
baseline, showing an attachment gain of 1.94 ± 0.27 mm that was statistically significant (P < 0.0001) [Table 1 and Figure 1d]. For test group at baseline, the mean CAL was 3.73 ± 0.70, which was reduced to 1.13 ± 0.51 with respect to baseline, showing an attachment gain of 2.60 ± 0.19 mm that was statistically significant (P < 0.0001) [Table 1 and Figure 1d]. The difference in the mean CAL between the test and control groups was 0.10 ± 0.33 which was not statistically significant (P > 0.05) [Table 2 and Figure 1d].

**Improvement in recession depth (X)**

The mean improvement in RD for control group was 1.53 ± 0.64 mm and 1.53 ± 0.64 mm for the test group. Improvement in RD was more in test group when compared to that of control group but did not reach any significance statistically (P > 0.05) [Table 3 and Figure 1e].

**Percentage of root coverage**

The mean percentage of root coverage for the control group was 56.22% ± 10.22% and 58.33% ± 12.19% for the test group. The difference between the percentages in the test and control groups did not reach any significance statistically (P > 0.05) [Table 3 and Figure 1f].

**DISCUSSION**

In patients with varying oral hygiene standards, gingival recession causes unpleasant esthetics and root sensitivity, hence the treatment of buccal gingival recession has become a regular routine.[3] There was a greatest potential for reduction in gingival recession and complete RC while using CAF technique or combined procedures as revealed by several systematic reviews and meta-analyses.[3] Henceforth, till date, these are the treatments of choice.

An effective perio-plastic surgical treatment of choice for Miller’s Class I/II multiple recessions is the coronally placed flap with several patient benefits that include RC, esthetics, and predictable long-term results.[10] The main goal and advantage of incorporating GTR to RC procedure is to achieve periodontal regeneration that results in new attachment rather than connective tissue repair.[10] The predominant protein found in alveolar bone and periodontal connective tissues is collagen. The main advantage of collagen when used as a GTR-based RC procedure is its hemostatic function and apart from that, collagen has a chemotactic function for fibroblasts that aids in cellular migration and attachment to facilitate primary wound closure, an important requirement for successful GTR outcomes.[10]

Considering the above-mentioned facts, the aim of this randomized, controlled, split-mouth clinical study was to evaluate the clinical outcome of RC in the treatment of Miller’s Class I and II recession defects in maxillary anterior and premolars CAF with and without RCM (Novabone RCM™, [Figure 3f]).[10] The CAF design used in this study was similar to that described by de Sancis and Zucchelli that involved the use of vertical releasing incisions and a split-full-split-thickness flap design.[10] A split-full-split-thickness flap design includes the partial thickness of the surgical papillae that facilitates the nutritional exchanges between them and the underlying de-epithelialized anatomical papillae, and it also improved the blending (in terms of color and thickness) of the surgically treated area with respect to adjacent soft tissues; the periosteum in the central portion of the flap so as to maximize soft tissue thickness over the avascular root surface. To increase the predictability of achieving adequate coronal positioning and complete defect coverage, vertical incisions were used. In similar studies by Felipe et al.,[11] and Papageorgakopoulos et al.,[11] a CAF with releasing incisions was compared to an envelope flap without releasing incisions. The procedure with releasing incisions resulted in achieving a significantly greater percentage of defect coverage (95%) than the procedure without releasing incisions (78%).

The more coronal level of the gingival margin after suturing, the greater the probability of complete RC as per a study done by Pini Prato et al.[13] Similarly, in the present study, the membrane was covered completely by the flap and was coronally positioned and sutured.
There were reductions in RD and PPD both in the test and the control groups in the present study. Hence, the decrease in PD suggested that the gain in CAL was associated with new connective tissue attachment. In both the groups, the mean KTH showed a significant increase. The KTH gain should be correlated with tissue maturation following healing and the fact that the mucogingival junction tends to be located at its genetically determined position. An increase in KTH may be because of granulation tissue formation from periodontal ligament tissue with the potential to induce keratinization of covering epithelium. These findings were in accordance with Praveen et al. (2010) and Cardaropoli et al. (2010). These findings were in accordance with Praveen et al. (2010) and Cardaropoli et al. (2010).

CAL showed attachment gains of 1.94 ± 0.27 mm and 2.60 ± 0.19 mm in the control and the test groups, respectively. Clinical improvement in the present test group was probably based on true periodontal regeneration whereas the improvement in control group was probably based on the formation of long junctional epithelium.

CONCLUSION

The present study gives a thorough understanding into the application of principles of GTR using RCM with CAF procedure for the treatment of gingival recession. The results of the present study suggest that CAF and CAF + RCM both can be successfully used to treat Miller’s Class I and Class II gingival recession defects with overall significant improvement in all the assessed clinical parameters. The results of the study found no significant difference between two groups with regard to the outcome of the treatment.

More studies are required in future to compare the results obtained by the proposed technique with other perio-plastic surgical techniques with longer follow-up, and involving larger sample size is warranted to evaluate whether RCM provides better and stable results. Furthermore, histological evaluation is necessary to assess the type of attachment obtained with the use of RCM.

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Conflicts of interest
There are no conflicts of interest.

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