Original Article

Comparative evaluation of envelope type of advanced flap with and without type I collagen membrane (NEOMEM™) in the treatment of multiple buccal gingival recession defects: A clinical study

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Abstract

Background: The aim of this study is to compare and evaluate the clinical outcome of the envelope-type of coronally advanced flap (CAF) alone versus envelope type of coronally advanced flap plus type I collagen membrane (NEOMEM) in the treatment of multiple buccal gingival recessions, using the split mouth study. **Materials and Methods:** Ten patients in the age group of 20-50 years showing bilateral gingival recessions were treated. The defects in each patient were randomly assigned as Group A, which were treated with the envelope type of CAF, and those in Group B were treated with envelope type of CAF along with the Type I collagen membrane (NEOMEM). The recession depth (RD), probing depth (PD), clinical attachment level (CAL), and width of the keratinized tissue (KT) were measured at baseline, at three and six month intervals. **Results:** Forty-six Miller's class I and II gingival recessions were treated. In the CAF + Type I collagen membrane (NEOMEM)-treated (Group B) sites the baseline gingival recession was 2.34 ± 0.48 mm, while in the CAFtreated (Group A) sites it was 2.52 ± 0.84 mm. Both the treatments resulted in significant recession depth reduction ($P < 0.001$), but the reduction was significantly greater ($P < 0.01$) for Group B than Group A. The probing depth changes were significant ($P < 0.01$) for both groups, but the difference was nonsignificant. Similarly, a significant gain of CAL was seen in Group B (2.23 ± 0.75 mm, $P < 0.001$) as well as in group A (1.60 ± 0.86 mm, $P < 0.001$) showing a significant difference ($P < 0.01$) between the two groups. The width of keratinized tissue was also significantly ($P < 0.001$) increased in both groups, but the increase was significantly greater ($P < 0.001$) in group B (2.30 ± 1.06 mm) than in group A (1.21 ± 0.67 mm). **Conclusion:** The envelope type of CAF along with Type I collagen membrane (NEOMEM) was more effective than envelope type of CAF alone, in producing root coverage in multiple gingival recession defects, associated with gain in CAL as also in the width of KT.

Key words: Collagen membrane, guided tissue regeneration, keratinized tissue

INTRODUCTION

Among the various mucogingival problems, gingival recession is the most common clinical entity observed in the population, regardless of their age and ethnicity. The treatment of buccal gingival recession for esthetics or root sensitivity is a frequent demand in patients with a high standard of oral hygiene.[1]

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Gingival recession can be found in a large proportion of the population both in the elderly and young adults, in subjects with or without high levels of oral hygiene, and at single or multiple teeth.[2] Tissue trauma caused by vigorous toothbrushing is considered to be the predominant cause for the development of recessions, particularly in young individuals, while periodontal disease may be the primary cause in older adults.[3] The frequency of gingival recession increases with age.[4] At an early age, gingival recession from toothbrushing is more prevalent in females than in males. This gender difference gradually disappears and in fact inverts later in life when males are more prone to practice

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traumatic toothbrushing habits.[5] Gingival recession occurs most frequently on maxillary cuspids and bicuspids, on the buccal tooth surfaces.[6] More buccal gingival recessions are noted on the left side of the jaws, presumably because a majority of the individuals are right-handed and clean more thoroughly on the left side. This indicates that the occurrence of gingival recession is due to oral hygiene procedures.[7] Therefore, changing the toothbrushing technique should be considered as the first step in the treatment of gingival recession patients.

A variety of techniques have been proposed to cover multiple gingival recession defects. These include coronally or laterally positioned pedicle grafts, epithelialized free tissue grafts and connective tissue grafts. The Connective Tissue Graft (CTG) technique is considered as the gold standard in the management of recession defects. However, the effectiveness of the CTG procedure in the treatment of multiple recessions may be limited due to the great discomfort to the patient when large grafts are harvested from the palatal mucosa. Also, large grafts can impair vascular exchange between the covering flap and the underlying receiving bed, and thus, increase the risk for flap dehiscence and unesthetic exposure of the graft. The coronally advanced flap is a root coverage surgery that does not involve a palatal donor site and it has been demonstrated to be a safe and predictable approach.[8,9]

Multiple gingival recessions are successfully treated by means of the envelope type of CAF. Root coverage and esthetic outcomes with this procedure are good in the long term.[8,9] Envelope type of coronally advanced flap was described by Zucchelli and De Sanctis in 2000. The presumed advantage of envelope type of flap is the lack of vertical releasing incisions (VRIs), which can damage the lateral blood supply to the flap and may result in unesthetic visible white scars (keloids). The absence of VRIs helps limit bleeding during surgery and favor blood clot stabilization. Patients treated with the envelope type of coronally advanced flap have an excellent color and contour match of the gingiva.[9] Recent case reports and clinical trials have indicated that the outcome of coronally advanced flap procedures can be augmented by supporting the flap with a membrane.[5] This procedure is known as the guided tissue regeneration (GTR) procedure.

The guided tissue regeneration procedure can achieve highly predictable and highly esthetic root coverage, without the disadvantage of requiring a second surgical site or procedure.[10] The GTR technique has various advantages, such as, good esthetics, potential for regeneration of the lost periodontal attachment, no need of a second surgical site, and fewer post surgical complications.[11]

The purpose of the present study is to compare and evaluate the clinical outcome of the envelope type of coronally advanced flap (CAF) alone versus envelope type of coronally advanced flap plus type I collagen membrane (NEOMEM™), in the treatment of multiple buccal gingival recessions, using the split mouth study.

MATERIALS AND METHODS

Ten periodontally and systemically healthy patients in the age group of 20-50 years (both male and female) visiting the Department of Periodontics, Punjab Government Dental College and Hospital, Amritsar, between April 2011 and May 2012, with bilateral, almost comparable multiple Miller's Class I or Class II buccal recession defects, ≥2 mm in anteriors and/or premolars, were enrolled in the study. These patients had either esthetic or sensitivity complaints, due to multiple gingival recession defects. The patients agreed to participate in the study and gave their written informed consent on a consent form. The study was approved by the Ethical Committee of the Punjab Government Dental College, Amritsar. Recession defects associated with caries, deep abrasion or restoration, and teeth with evidence of pulpal pathology were excluded. The exclusion criteria also involved smokers, un-cooperative patients and persons on medications, as these were known to interfere with periodontal tissue healing.

Study design: The study was a randomized controlled clinical trial, comparing the envelope type of CAF alone versus the envelope type of CAF plus type I collagen membrane (NEOMEM™) in the treatment of multiple buccal gingival recessions. A 100%, Type I absorbable collagen membrane, prepared from purified bovine Achilles tendon (NEOMEM™) provided by Citagenix Inc, Montreal, Quebec, was used for Group B defects. The study protocol involved a screening appointment to verify the eligibility followed by initial therapy, to establish optimal plaque control and gingival health conditions, surgical therapy, a maintenance phase, and a postoperative evaluation at three-month and six-month intervals after surgery.

The defects in each patient were randomly assigned as either Group A (control side), which were treated with envelope type of CAF or Group B (test side),

which were treated with envelope type of CAF along with Type I collagen membrane (NEOMEM™).

After the screening examination, all the subjects received a session of prophylaxis, including instructions on proper oral hygiene measures, scaling, and professional tooth cleaning, with a rubber cup and a low abrasive polishing paste. A coronally directed roll technique was prescribed for teeth with recession defects, to minimize toothbrushing trauma to the gingival margin. All measurements were carried out by a single examiner. The following clinical measurements were taken one week before surgery, and at the three-month and six-month follow-up visits, at the mid-buccal aspects of the teeth: Gingival recession depth (RD), measured from the cementoenamel junction (CEJ) to the most apical extension of the gingival margin; probing depth (PD), measured from the gingival margin to the bottom of gingival sulcus; The clinical attachment level (CAL), measured from the CEJ to the bottom of gingival sulcus; and width of keratinized tissue (KT), the distance between the gingival margin and the mucogingival junction. All measurements were performed with a manual probe and rounded up to the nearest millimeter [Figure 1].

Surgical procedure

Control group: The surgical technique adopted was an envelope type of coronally advanced flap proposed by Zucchelli and De Sanctis [Figure 2]. Following local anesthesia, a horizontal incision was made with a scalpel to design an envelope flap. The horizontal incision of the envelope flap consisted of submarginal incisions in the interdental areas, which continued with the intrasulcular incision at the recession defects. Each surgical papilla was dislocated with respect to the anatomical papilla by the oblique submarginal interdental incision. The envelope flap was raised with a split-full-split approach in the coronal–apical direction [Figure 3]. To dissect the surgical papilla in a split-thickness manner, oblique interdental incisions were carried out, keeping the blade parallel to the long axis of the teeth.The gingival tissue apical to the exposure was raised in a full thickness manner. Finally, the most apical portion of the flap was elevated in a split thickness manner to facilitate coronal displacement of the flap. The root surfaces were scaled, planed, and conditioned with Ethylenediaminetetraacetic acid (EDTA) (pH 7), to eliminate the smear layer from the dentine tubuli and to improve the coagulum adhesion to the root surface. The remaining tissue of the anatomical interdental papilla was de-epithelialized to create a connective tissue bed, to which the surgical papilla was sutured [Figure 4]. The flap was repositioned coronally and secured with 3-0 silk sutures [Figure 5]. Periodontal pack was placed to protect the surgical site [Figure 6].

Test group: The surgical technique was the same as for the control group. After de-epithelialization and coronal advancement of the flap, the NEOMEM™ collagen membrane was trimmed to the appropriate size according to the size of defects after correct manipulation. It was then placed over the naked root surface and sutured using 5-0 polyglactin 910 (Vicryl™) suture [Figure 7]. Finally, the flap was coronally positioned over the membrane and anchored by 3-0 silk sutures. Periodontal pack was placed to protect the surgical site.

The postoperative pain and edema were controlled with ibuprofen. Systemic antibiotics were given orally, thrice daily, for one week, postoperatively. The patients were instructed not to brush their teeth in the treated area and advised to rinse with 15 ml of chlorhexidine solution (0.12%) thrice a day, for two weeks. After this period, the patients were re-instructed in the

Figure 1: Incision design (AP - Anatomical papilla, SP - Surgical papilla)

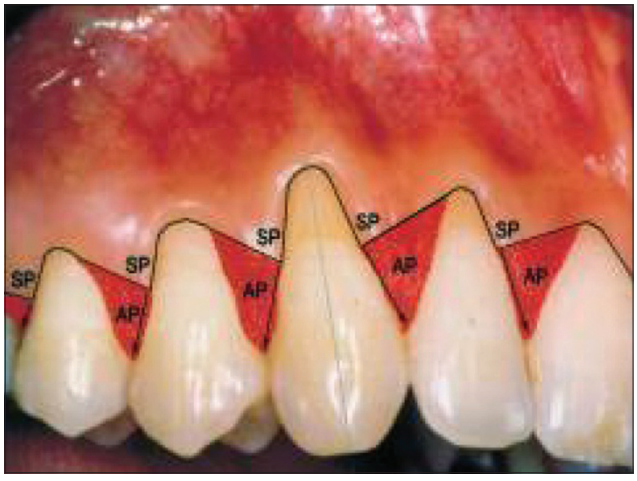

Figure 2: Preoperative photograph

Figure 3: Flap elevation

Figure 4: De-epithelialization of anatomical papillae

Figure 5: Membrane adapted and then sutured over the denuded root surface

Figure 6: Flap advanced coronally and sutured

Figure 7: Periodontal pack placed

mechanical cleaning of the treated teeth, and used an ultrasoft toothbrush and roll technique for one month. The sutures were removed after 10 days. All the patients were recalled for prophylaxis, two and four weeks after suture removal and once every two months, until the final examination.

Statistical analysis

Descriptive statistics were expressed as the mean ± standard deviation for each parameter. Clinical parameters at the baseline, three months, and six months, were compared using the nonparametric Mann Whitney U test (intergroup comparison) and Wilcoxon test (intragroup comparison).

RESULTS

All patients tolerated the surgical procedures well, experienced no postoperative complications, and complied with the study protocol.

A total of 46 Miller's class I and II gingival recessions were treated. Out of these, 23 recession defects of one side were treated using CAF alone, involving four lateral incisors, nine cuspids, eight first pre-molars, and two second premolars; and 23 recession defects of the other side involving similar teeth were treated using CAF + Type I collagen membrane (NEOMEM™).

Gingival recession depth: In the (Group A) CAF-treated sites, the baseline gingival recession was 2.52 ± 0.84 mm, while in the (Group B) CAF + Type I collagen membrane (NEOMEM™)-treated sites, it was 2.34 ± 0.48 mm. At three months the recession depth reduction in group A was 1.82 ± 0.49 mm ($P < 0.001$) and in group B it was 2.04±0.56 mm ($P < 0.001$). At six months, the extent of root coverage achieved at three months was slightly reduced in both groups, but this change was significant ($P < 0.01$) in group A and nonsignificant in group B. Both treatments resulted in significant greater recession depth reduction ($P < 0.001$), amounting to an average 1.30 ± 0.63 mm in group A and 1.82 ± 0.49 mm in group B at the six-month follow-up, but the reduction was significantly greater ($P < 0.01$) for group B than group A [Table 1] [Figures 8-15].

Probing depth: At baseline, the probing depth measurements were 1.21 ± 0.42 mm in group A and 1.21 ± 0.42 mm in group B. The probing depth changed for both treatment groups from baseline to three months, but the changes were not significant. At the six-month follow-up, the probing depth changes were significant ($P < 0.01$) for both the treatments and the difference between the two groups was nonsignificant [Table 2].

Clinical attachment level: At three months there was a mean gain of clinical attachment in Group A of 2.06 ± 0.75 mm ($P < 0.001$) and in Group B

Table 1: Intergroup Comparison of mean change in clinical recession depth at various time intervals

Time	Group A	Group B	Difference Mean±SE	*P* value
Baseline to 3 months	1.82±0.49	2.04±0.56	−0.21±0.15	0.173^{NS}
Baseline to 6 months	1.30±0.63	1.82±0 0.49	−0.52±0.16	0.002**
3 months to 6 months	−0.52±0.51	−0.21±0.51	−0.3043±0.15	0.023^{NS}

NS: *P*>0.05 (Not Significant), *: *P*<0.05 (Significant at 5% Significance level), **: *P*<0.01 (Significant at 1% Significance level), ***: *P*<0.001 (Highly Significant). *Mann Whitney U test was used to obtain *P* value of this data as the data was not normally distributed, SE: Standard error

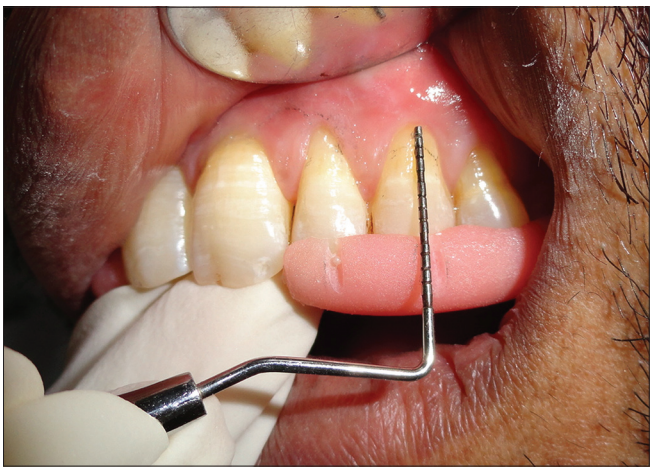

Figure 8: Preoperative photograph of case 1 (non-membrane side)

Figure 9: Preoperative photograph of case 1 (membrane side)

Figure 10: Postoperative photograph of case 1 (non-membrane side)

Figure 11: Postoperative photograph of case 1 (membrane side)

Figure12: Preoperative photograph of case 2 (non-membrane side)

Figure 13: Preoperative photograph of case 2 (membrane side)

Figure 14: Postoperative photograph of case 2 (non-membrane side)

Table 2: Intergroup comparison of mean change in probing depth at various time intervals

Time	Group A	Group B	Difference Mean±SE	*P* value
Baseline to 3 months	0.23±0.39	0.15±0.46	0.08±0.12	0.054^{NS}
Baseline to 6 months	0.30±0.41	0.41±0.46	−0.10±0.13	0.409^{NS}
3 to 6 months	0.06±0.27	0.26±0.42	−0.19±0.10	0.088^{NS}

NS: *P*>0.05 (Not Significant), *: *P*<0.05 (Significant at 5% Significance level), **: *P*<0.01 (Significant at 1% Significance level), ***: *P*<0.001 (Highly Significant). *Mann Whitney U test was used to obtain *P* value of this data as the data was not normally distributed, SE: Standard error

of 2.19 ± 0.77 mm ($P < 0.001$). At six months, the gain in clinical attachment in Group A was 1.60 ± 0.86 mm ($P < 0.001$) and in Group B was 2.23 ± 0.75 mm ($P < 0.001$). Measurements using the Mann Whitney U test revealed a non-significant change in CAL between the two groups at three months, but the difference was significantly ($P < 0.01$) greater at six months with more gain in CAL in Group B than Group A [Table 3].

Width of the keratinized tissue: The width of keratinized tissue at baseline was 4.13 ± 1.63 mm in Group A and 4.26 ± 1.45 mm in Group B. At three months there was a significant ($P < 0.001$) increase in the width of KT in both groups, with a 1.13 ± 0.62 mm increase in group A and 1.69 ± 0.92 mm increase in Group B. The difference between the two groups at three months was somewhat significant ($P > 0.05$). At six months there was a significant ($P < 0.001$) increase in the width of KT in both the groups, but the increase was significantly greater ($P < 0.001$) in the membrane group (2.30 ± 1.06) than in the non-membrane (1.21 ± 0.67) group at the six month follow-up [Table 4].

Figure 15: Postoperative photograph of case 2 (membrane side)

DISCUSSION

A variety of techniques have been proposed to cover multiple gingival recession defects. These include coronally or laterally positioned pedicle grafts, epithelialized free tissue grafts, and connective tissue grafts. The correct choice of flap design is an important step toward obtaining satisfactory root coverage outcomes.[12] In patients with high esthetic expectations CAF is the first choice, when there is adequate keratinized tissue apical to the root

Table 3: Intergroup comparison of mean change in clinical attachment level at various time intervals

Time	Group A	Group B	Difference Mean±SE	*P* value
Baseline to 3 months	2.06±0.75	2.19±0.77	−0.13±0.22	0.538[NS]
Baseline to 6 months	1.60±0.86	2.23±0.75	−0.63±0.23	0.007**
3 to 6 months	−0.45±0.47	0.04±0.54	−0.50±0.15	0.002**

(−) indicates increase in clinical attachment level, NS: *P*>0.05 (Not Significant), *: *P*<0.05 (Significant at 5% Significance level), **: *P*<0.01 (Significant at 1% Significance level), ***: *P*<0.001 (Highly Significant). *Mann Whitney U test was used to obtain *P* value of this data as the data was not normally distributed, SE: Standard error

Table 4: Intergroup comparison of mean change in width of keratinized tissue at various time intervals

Time	Group A	Group B	Difference Mean±SE	*P* value
Baseline to 3 months	−1.13±0.62	−1.69±0.92	0.56±0.23	0.027*
Baseline to 6 months	−1.21±0.67	−2.30±1.06	1.08±0.26	0.000***
3 to 6 months	−0.08±0.28	−0.60±0.65	0.52±0.14	0.001**

(-) indicates increase in width of keratinized gingiva. NS: *P*>0.05 (Not Significant), *: *P*<0.05 (Significant at 5% Significance level), **: *P*<0.01 (Significant at 1% Significance level), *** : *P*<0.001 (Highly Significant). *Mann Whitney U test was used to obtain *P* value of this data as the data was not normally distributed, SE: Standard error

exposure. Multiple gingival recessions affecting the esthetic areas of the mouth are successfully treated with the envelope type of CAF. The main advantage of the envelope type of flap is the lack of vertical releasing incisions, which can damage the lateral blood supply to the flap and may result in unesthetic visible white scars.[9] Recent case reports and clinical trials have indicated that the outcome of coronally advanced flap procedures can be augmented by supporting the flap with a membrane.[5]

The present study showed that envelope type of coronally advanced flap along with Type I collagen membrane (NEOMEM™) was more effective in producing root coverage in multiple adjacent gingival recession defects, resulting in significant root coverage at three and six months (87.17 and 77.77%, respectively) than the envelope type of CAF alone (71.22% at three months and 51.58% at six months). This finding was similar to studies using bioresorbable membranes, which showed a mean defect coverage ranging from 45 to 94%, with the mean of all studies being 72% (Pini Prato *et al*., 1992[13] (73%), Amarante *et al*., 2000,[5] Boltchi *et al*., 2000[10] (33 to 100%), and Genon, 2001[11] (74%)). The Guided Tissue Regeneration technique could offer several advantages over other techniques, including elimination of the need for a second surgical site for harvesting a graft and its associated morbidity, less postsurgical trauma and discomfort, and an increase in acceptance of the procedure by the patients.[14]

The mean reduction in recession depth in Group A was 1.82 ± 0.49 mm at the end of three months and 1.30 ± 0.63 mm at the end of six months, both of which were statistically significant ($P < 0.001$). This recession depth reduction could be attributed to the surgical technique (envelope type of Coronally Advanced Flap), which involved the split-full-split thickness elevation of the flap. The split thickness elevation at the level of the surgical papilla guaranteed anchorage and blood supply in the interproximal areas, mesial and distal to the root exposure, facilitated nutrient exchange between the surgical papillae and de-epithelialized anatomical papillae, and improved blending (in terms of color and thickness) of the surgically treated area, with respect to the adjacent soft tissue. Full thickness portion, by including the periosteum, confers more thickness, and thus, a better opportunity to achieve root coverage, to that portion of the flap residing over the previously exposed avascular root surface. The more apical split thickness flap elevation facilitates passive coronal displacement of the flap (De Sanctis M, 2007.[15]). The mean reduction in recession depth in group B was 2.04 ± 0.56 mm at the end of three months and 1.82 ± 0.49 mm at the end of six months, both of which were also statistically highly significant ($P < 0.001$). On comparison, Group B showed better recession depth reduction than Group A. The intergroup comparison results showed that there was no significant difference from baseline to three months but the results were significant at 1% significance level ($P < 0.01$) at six months. The significant difference in results at six months can be attributed to the design characteristics of the collagen membrane (NEOMEM™) and advantages of the envelope type of CAF, both of which, when combined in Group B, favored better root coverage in Group B as compared to Group A, in which only envelope type of CAF was performed (Boltchi FE *et al*., 2000[10], Zucchelli, 2000[8]). It can also be speculated that the collagen membrane inhibits the apical migration of the epithelium, stabilizes the wound and augments tissue thickness, which increases the long-term stability of the marginal tissue (Lee EJ *et al*., 2002).[16]

Data from this study demonstrated that the probing depth showed a nonsignificant change at three months and a significant ($P < 0.01$) decrease at six months, in both groups. On comparison, group B showed better probing depth reduction than group A, but the difference was nonsignificant. This finding was in accordance with the study by Genon *et al*., 2001,[11] which showed that the GTR procedure could create a more resistant attachment. This could also be attributed to the presence of collagen, which formed a major portion of the NEOMEM™ collagen membrane. Collagen stimulated platelet attachment, enhanced

fibrin linkage, and was chemotactic for fibroblasts. It stabilized wound leading to better tissue maturation, which resulted in a stable attachment of the covering flap to the previously denuded root surface (Lee *et al*., 2002).[16]

With regard to the clinical attachment level (CAL), there was significant ($P < 0.001$) gain in CAL, in both groups, at the three-month and six-month follow-up. On comparison, both groups showed a similar gain in CAL at three months, but at six months the membrane group (Group B) showed a significant ($P < 0.001$) gain in CAL compared to the non-membrane group (Group A). The reason behind the improved results in Group B could be the design characteristics of the collagen membrane, that is, the scalloped cervical outline which integrated better with the flap margin and the more passive coronal advancement of the flap to cover the collagen membrane preventing membrane exposure (negatively affect the final outcome) in the postoperative period, which favored better healing, better root coverage, and thus, more clinical attachment gain (Boltchi *et al*., 2000).[10] Also according to Lee *et al*., 2002,[16] the collagen membrane not only increased the tissue thickness via membrane integration with the flap, but also protected the initial attachment gain. This could be attributed to the ability of the membrane to create space for the PDL/bone cells to promote tissue regeneration. The collagen membrane inhibited the apical migration of the junctional epithelium, allowing undifferentiated mesenchymal cells to repopulate the wound area and promote regeneration of a new bone, cementum, and connective tissue attachment, resulting in the stable attachment of the covering flap over the previously denuded root surface.[17]

The width of keratinized tissue (KT) measurements demonstrated a significant ($P < 0.001$) increase in both groups at the three-month and six-month follow-ups. The increase in width of the keratinized tissue in both the groups could be attributed to the apical shift of the mucogingival junction, as compared to its location after the coronally advanced procedure. Studies by Trombelli *et al*., 1998,[18] demonstrated that the shift of the mucogingival junction to its genetically determined position resulted in the increase in width of the keratinized tissue. The increase in width of the keratinized tissue could be explained by several events taking place during the healing and maturation of the marginal tissue (Wennstrom, 1996).[19] These events were related to the inductive stimulus from the underlying connective tissue on the differentiation of the keratinized gingival epithelium (Karring *et al*., 1974),[20] granulation tissue formation derived from the periodontal ligament tissue, which could contribute to the increased dimension of the gingiva (Karring *et al*., 1975),[21] and to the tendency of the mucogingival line to regain its original genetically determined position (Trombelli *et al*., 1998).[18] On comparison at three months, Group B showed a slightly more significant (<0.05) increase than group A, but the increase in width of KT was highly significant in group B as compared to group A after a six-month interval.

CONCLUSION

The envelope type of coronally advanced flap along with Type I collagen membrane (NEOMEM™) was more effective in producing root coverage in multiple gingival recession defects and was associated with more gain in the clinical attachment level and in the width of the keratinized tissue, than in the envelope type of coronally advanced flap alone.

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