



Original Research Article

The efficacy of amnion Chorion allograft in management of type 1 gingival recession. (Randomized clinical trial)

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Abstract: Background: Root coverage and pleasing aesthetics are the required outcomes of gingival recession treatment. Multiple modalities reach these outcomes but still the added value of coronally advanced flap (CAF) and subepithelial connective tissue graft (SCTG) is considered the gold standard for recession treatment in isolated defects. Aim: To evaluate the therapeutic effectiveness of amnion chorion membrane (ACM) with CAF in managing isolated type 1 gingival recession (RT1) defects. **Patients and methods:** 28 patients with isolated RT1 defects were selected and randomly assigned into two groups. Group A: treated with CAF and ACM while group B: treated with CAF and SCTG **Results:** both groups showed significant improvement at 3, and 6 months in all clinical parameters from baseline measurements. No statistical significance was found in the inter group analysis regarding physical parameters. However, Group A showed significant difference in patient reported outcomes results when compared to group B. **Conclusion** In isolated RT1, ACM can be used as suitable substitute to SCTG.

Keywords: Amnion, chorion, allografts

INTRODUCTION

While health and function were usually the required

outcomes of any dental treatment, aesthetics and comfort are now critical for any treatment to be

considered successful. Gingival recession is a common mucogingival deformity that affects a large group of individuals, especially nowadays with the increased life expectancy. It is defined by the apical migration of the marginal gingiva tissue relative to the cemento-enamel junction (CEJ), resulting in exposure of the root surface.(1)

Bad oral hygiene, traumatic tooth brushing, orthodontic movement, and anatomical factors such as frenulum pull, and thinner tissue phenotype are among many common risk factors for gingival recession. (2)

Numerous classification systems have emerged across the literature to enhance the diagnostic accuracy of gingival recession. Among these, Miller's Classification has historically been the most extensively adopted and referenced framework but due to many limitations it is currently replaced by Cairo classification. Cairo et al, classified recession defects (RT) into three classes according to interproximal clinical attachment loss (CAL) measured from CEJ. RT1: a recession defect with no interproximal CAL. RT2: a recession defect with interproximal CAL that is less than or equal to facial CAL. RT3: a recession defect that is more than interproximal CAL.(3)

The therapeutic approach to gingival recession defects is primarily undertaken to improve esthetic outcomes, mitigate dentinal hypersensitivity, and promote the establishment or augmentation of keratinized gingival tissue. Furthermore, root coverage techniques are necessary for addressing root abrasion or caries, as well as for rectifying the disharmony or inconsistency of the gingival margin.(4)

A range of surgical modalities has demonstrated efficacy in the management of gingival recession, regardless of the specific method employed, as long as the biological prerequisites for obtaining root coverage are met. The selection of a specific surgical technique is influenced by a range of factors, including clinical characteristics of the defect and individual patient preferences.(5)

The combined use of coronally advanced flap (CAF) and subepithelial connective tissue graft (SCTG) is widely regarded as the gold standard surgical approach for the management of isolated gingival recession defects.(6)

However, obtaining a SCTG requires harvesting from a donor site usually the hard plate. This procedure adds much time to surgical procedure itself and carries the risk of bleeding as well as increased pain (7) . The increased morbidity and patient dissatisfaction with this step encouraged the

search for other biomaterials to replace SCTG (8).

Various biomaterials have been proposed as alternatives to SCTG; however, current literature continues to support using SCTG, particularly due to its benefits in enhancing gingival thickness and promoting keratinization.(9)

The incorporation of placental allograft into oral and periodontal surgery has emerged recently. These biomaterials are abundant in growth factors, stem cells, and cytokines. Their notable anti-inflammatory, angiogenic, and regenerative properties have led to a surge in research focus. Their safety has been established through consistent application in both the medical and dental fields. These placental allografts were amnion, chorion or both amnion chorion allografts. While many studies compared both amniotic membrane (AM) and chorionic membrane (CM) to SCTG, only a few studies compared the added value of both membranes to SCTG (10)

This study addresses the use of placental allograft with CAF in management of isolated recession. The placental allograft consists of a dehydrated human amnion chorion membrane(dH-ACM) that retains both layers of placenta with their regenerative properties. In addition, it compares its efficacy in comparison to SCTG

MATERIALS AND METHODS

Ethical regulations:

Prior to study enrollment, all participants received a comprehensive explanation of the treatment protocol, encompassing procedural steps, potential risks, and anticipated outcomes. Informed consent was obtained in writing from each patient. The study was conducted in accordance with the International Conference on Harmonization Good Clinical Practice (ICH-GCP) guidelines, the ethical principles outlined in the Declaration of Helsinki, and was approved by the Research Ethics Committee of the Faculty of Dentistry, University which approved research proposal at its 101-committee meeting with decision number 857. This investigation was structured as a randomized, controlled clinical trial employing a double-blind methodology with parallel treatment arms and it was followed the CONSORT statement (<http://www.consort-statement.org/>) (Figure) 1.

Patient selection:

This clinical investigation included 28 patients diagnosed with Type I gingival recession defects. Participants were recruited from the outpatient clinic of the Department of Oral Medicine, Oral Diagnosis, and Periodontology at the Faculty of Dentistry. Eligibility criteria required systemically healthy individuals aged between 25 and 45 years, demonstrating full-mouth bleeding scores (FMBS)

and full-mouth plaque scores (FMPS) below 15%, and presenting either with a clinical indication or a patient-driven request for recession coverage. Exclusion criteria comprised pregnant individuals, tobacco users, patients with special needs or psychiatric disorders, and those with a prior history of periodontal surgical intervention in the affected area.

Sample size calculation

This power analysis used root coverage % as the primary outcome. Based upon the results of Maity S and Priyadharshini V (2023), the mean (SD) values were 66.17 (18.85) and 87.17 (18.33) % for the two groups, respectively. The resulting effect size (d) was 1.13. Using alpha (α) level of 5% and Power of the study = 80%; the minimum estimated sample size 14 subjects per group. Sample size calculation was performed using G*Power Version 3.1.2.2.

randomization

28 patients assigned randomly by computer software (<https://www.randomizer.org/>) into two groups. Participants received their allocated treatment randomly through a concealed letter.

Group A contains 14 patients and was treated by CAF and dh-ACM (bioclude, snoasis medical, Denver, Co.USA). fig 2

Group B contains 14 patients and was treated by CAF and SCTG.

clinical measurements

Comprehensive clinical periodontal parameters were systematically recorded at baseline, and subsequently at 3-month and 6-month follow-up intervals, by a single calibrated masked periodontist. Clinical parameters included: Plaque index (PI), Gingival index (GI), probing depth (PD), recession depth (RD), recession width (RW), Clinical attachment loss (CAL), the height of keratinized gingiva (HKG), and Gingival thickness (GT). All the recordings were measured using UNC-15 probe and rounded to nearest half of millimeters.

GT was measured by locating whether a periodontal probe was shown from gingival sulcus or not.

Recession esthetic score and the percentage of root coverage for every patient was carried out at 6 months post treatment.(11)

Patient reported outcomes (PROMS)

Pain, infection, and analgesic intake were assessed using a visual analogue scale (VAS) ranging from 1 to 10, and collectively evaluated as indicators of postoperative morbidity. in addition, recovery time in days was recorded as ability to eat freely without pain. Furthermore, patient aesthetic evaluation of

defects at baseline and 6 months and recorded by vas from 1 to 10.

Presurgical preparations

All participants received a non-surgical treatment consisting of full mouth debridement 1 month prior to surgical treatment. Oral hygiene measures were reinforced, and patients were motivated to maintain an adequate level of oral health. Proper brushing technique was shown as well. 4 weeks later baseline records were obtained, and participants received the allocated surgical treatment.

Surgical phase

The surgical protocol for the coronally advanced flap was applied as per the original description by Zucchelli and De Sanctis (12). All surgical procedures were done under 5x surgical loupe magnification.

For group A an ACM of appropriate size was secured at base of each de-epithelialized anatomical papillae by 6 0 interrupted polyglycolic acid (PGA) suture at the level of CEJ in test group. Figure 3

While group B, a de-epithelized connective tissue graft harvested from hard plate as a free gingival graft was secured as ACM. Figure 4

S-CTG dimensions were 6 mm plus recession width, 5 mm in height, and 1 mm in thickness.(13)The harvesting site was protected by gelatin sponge stabilized with cross sling suture. Figure 5

Post surgical instructions

To manage postoperative discomfort and minimize complications, patients received an initial dose of Cataflam 50 mg at the onset of surgery, with additional NSAID doses administered as needed. A prophylactic course of amoxicillin-clavulanic acid was prescribed for five days. Oral hygiene instructions included twice-daily rinsing with 0.12% chlorhexidine and avoidance of brushing the surgical site. Following suture removal, chlorhexidine rinsing continued for two weeks to maintain plaque control, and mechanical cleaning was initiated after one month. Patients were monitored through scheduled follow-up visits at two weeks, three months, and six months, during which professional prophylaxis and individualized oral hygiene instruction were provided.

Statistical analysis

Statistical analysis was performed with IBM® SPSS® (ver. 27. SPSS Inc., IBM Corporation, Armonk, NY, USA). Data was explored for normality using Shapiro-Wilk test. Quantitative data were presented by mean and standard deviation. Independent t test was used to compare means between the two groups. A repeated measure

ANOVA was used to compare means in each group across multiple times to see changes to an intervention with Bonferroni post hoc test for significant results. Chi square test was used to find

relationship between categorical variables. A statistically significant level was considered when p value < 0.05.

RESULTS

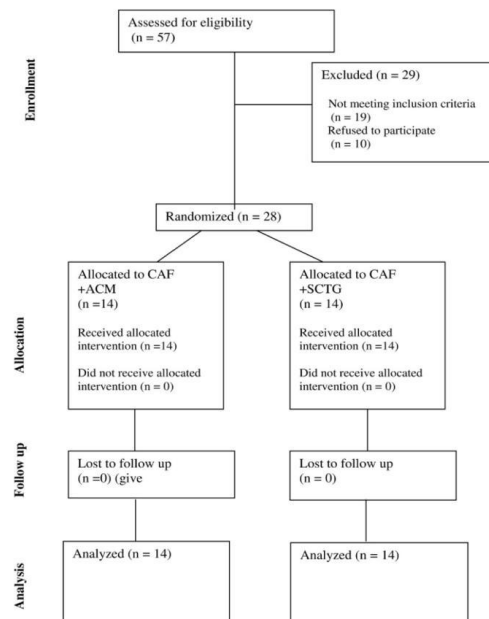


Figure 1: consort statement

Twenty-eight clinically healthy subjects diagnosed with isolated buccal gingival recession classified as Cairo RT1 were randomly allocated to one of two study groups. Group A (ACM) had 14 patients with 8 males and 6 females with mean age range is 29.92 ± 5.96 years while group B (SCTG) had 14 patients as well 7 males and 7 females with mean age range is 31.07 ± 5.48 years as shown in table 1.

Table (1): Baseline data of studied group

Variables	Groups		P value
	Group A (n= 14)	Group B (n= 14)	
Age	29.92±5.96	31.07±5.48	0.6
Sex			0.7
Males	8 (57.1%)	7 (50%)	
female	6 (42.9%)	7 (50%)	
Site			0.5
L canine	2 (14.3%)	4 (28.6%)	
L central	6 (42.9%)	4 (28.6%)	
L lateral	0 (0%)	1 (7.1%)	
L premolar	2 (14.3%)	2 (14.3%)	
U canine	2 (14.3%)	0 (0%)	
U premolar	2 (14.3%)	3 (21.3%)	

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Throughout study duration, both FMBS and FMPS were under 15% at baseline, 3 months and 6 months. Both recession depth and recession width demonstrated statistically significant reductions from baseline to the 3-month and 6-month follow-up periods across both study groups, as detailed in Table 2. Moreover, a continuous improvement in clinical attachment level was noted over the course of the study. In Group A, CAL values decreased from 3.50 ± 0.73 at baseline to 0.86 ± 1.26 at 3 months, and further to 0.71 ± 1.26 at 6 months. Similarly, Group B exhibited a reduction in CAL from 3.64 ± 0.66 at baseline to 0.84 ± 1.26 at 3 months, and 0.71 ± 1.26 at 6 months. Moreover, both HKG and GT exhibited statistically significant increases at the 6-month follow-up in both study groups, with no discernible intergroup differences, as presented in Table 2.

As illustrated in Table 3, Both treatment groups demonstrated a marked enhancement in root coverage percentages by the 6-month evaluation point. The mean range of recession esthetic score was 8.85 ± 1.87 for group A and 8.78 ± 1.96 for group B respectively.

AS for PROMS, Patients mean morbidity ranges were 4.0 ± 1.17 and 8.5 ± 1.08 for group A and B respectively. Recovery time mean values were 6.57 ± 1 for group A and 8.79 ± 1.15 for group B. patient overall esthetic evaluation score were 8.85 ± 1.65 and 9.07 ± 1.07 for group A and B respectively at 6 months.

Table (2): Clinical periodontal measurements across time in the studied groups

Clinical periodontal measurements of	Time			P value	Effect
	At baseline Mean $\pm$ SD	At 3 months Mean $\pm$ SD	At 6 months Mean $\pm$ SD		
Gingival Index Group A Group B	12.35 ± 1.94 12.35 ± 2.34	10.85 ± 1.35^a 10.42 ± 0.85^a	10.5 ± 1.16^b 10.35 ± 1.33^b	0.002* 0.006*	0.522 0.452
plaque Index Group A Group B	11.28 ± 1.26 12.42 ± 2.41	10.64 ± 1.15^a 10.85 ± 1.46	10.28 ± 1.06^b 10.35 ± 1.33^b	0.006* 0.006*	0.452 0.452
Probing depth Group A Group B	1.11 ± 0.34 1.11 ± 0.21	0.82 ± 0.24^a 0.89 ± 0.18^a	0.96 ± 0.13^c 1.00 ± 0.0	0.002* 0.005*	0.381 0.351
Recession depth Group A Group B	2.39 ± 0.86 2.64 ± 0.63	0.38 ± 0.69^a 0.19 ± 0.36^a	0.43 ± 0.85^b 0.21 ± 0.42^b	<0.001* <0.001*	0.791 0.938
Recession Width Group A Group B	2.57 ± 0.51 2.57 ± 0.51	0.73 ± 0.96^a 0.42 ± 0.58^a	$0.57 \pm 1.01^{b,c}$ $0.29 \pm 0.61^{b,c}$	<0.001* <0.001*	0.824 0.892
Clinical attachment loss Group A Group B	3.50 ± 0.73 3.64 ± 0.66	0.86 ± 1.26^a 0.84 ± 1.26^a	$0.71 \pm 1.26^{b,c}$ 0.71 ± 1.26^b	<0.001* <0.001*	0.808 0.837
Height of keratinized gingiva Group A Group B	1.85 ± 0.53 1.85 ± 0.36	3.18 ± 0.66^a 2.85 ± 0.77^a	$3.35 \pm 0.74^{b,c}$ $3.00 \pm 0.87^{b,c}$	<0.001* <0.001*	0.851 0.703
Gingival thickness Group A Group B	0.21 ± 0.42 0.28 ± 0.46	 	0.78 ± 0.42 0.93 ± 0.26	0.001* <0.001*	0.571 0.497

Table (3): Root coverage percentage at 6 months between groups

Root coverage percentage at 6 months Percentage	Groups		P value	Effect size (Cohen's d)
	Group A (n= 14) Mean ±SD	Group B (n=14) Mean ±SD		
	82.14±31.66	85.07±29.30	0.8	30.51

Figures

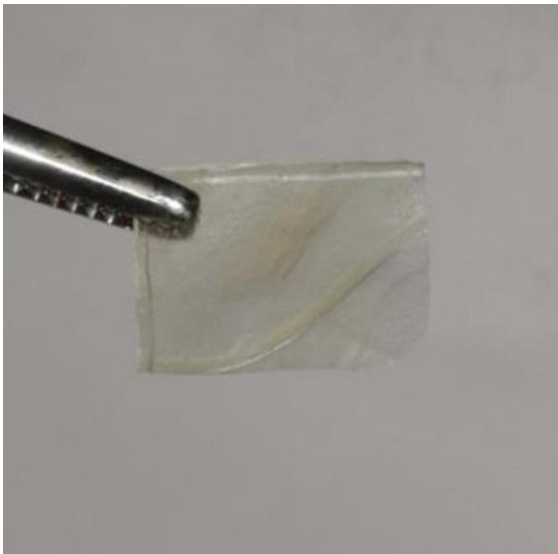


Figure 2



Figure 3



Figure 4

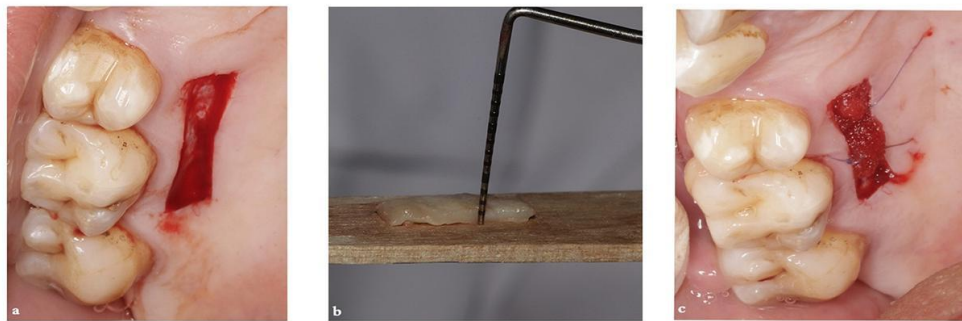


Figure 5

DISCUSSION

Among available surgical approaches, the integration of CAF with SCTG is broadly accepted as the most effective modality for managing RT1-type isolated gingival recession (14). However, the prolonged surgical time, the second surgical site, bleeding, inability to retreat, and discomfort associated with harvesting a SCTG derived the search for a suitable substitute. (13,15,16)

Placental allografts in the form of AM, CM, ACM, and amnion chorion amnion membrane (ACA) are among the considered substitutes. These allografts have regenerative, anti-inflammatory, anti-bacterial properties.(17) They have been used in oral and periodontal surgery with promising results. In addition, they have proven to show no adverse effects with minimum risk of contamination and cross infection.(18,19)

Although different preparations of these allografts are present, Dh-ACM was found to retain considerable biological properties due to unique Purion preparation technique.(20) This investigation sought to determine the therapeutic potential of combining amnion-chorion allograft with CAF for the management of isolated RT1-type gingival recession.

Clinical parameters showed statistically significant progression within each group when comparing baseline values to those recorded at 3 and 6 months postoperatively. Both groups maintained an appropriate level of oral hygiene throughout this study where FMPS and FMBS remained below 15%. These results suggests that ACM is biocompatible.(21)

The p value for probing depth reduction was decreased in both groups (0.002* and 0.005*) with insignificant intergroup change. The probing depth reduction results are similar to results described by Pradhan et al 2022, maity et al 2023. (22,23). However, another clinical trial compared AM to platelet rich fibrin showed insignificant PD reduction

in AM group. (24) The observed discrepancy could stem from the small sample size or the application of irradiated AM in earlier research, which differs biologically from the ACM used in this study.

Inter group comparison of RD and RW mean values were insignificant however, Intragroup analyses revealed substantial reductions in clinical parameters from baseline to both the 3-month and 6-month follow-up periods within each study group. These results are in accordance with Loganathan et al 2023, and maity et al 2023.(22,25) This as well within agreement with pereira et al 2023 and others. (21,23,26–28) These findings demonstrate the enhanced healing and regenerative characteristic of ACM.

Another significant finding was the increased band of attached tissue. Significant within-group improvements of the mean values were observed over the 6-month period, yet comparative analysis between the two groups demonstrated no statistically significant variation in the measured outcome. These results are consistent with de angelis et al 2025 who in a retrospective study evaluated the increased HKJ for five years follow up. (29)

Another clinical trial by gupta et al assessed AM and CM and their effects in gingival biotype. A notable enhancement in gingival thickness was observed in both study groups by the six-month evaluation point which was assessed by manual method and ultrasonographic method. (30) our qualitative evaluation of gingival thickness showed similar results with significant change in gingival phenotype.

The root coverage percentage was 82.14 in test group and 85.07 in control group. This was consistent with Elzanaty et al 2018.(31) However, this is with in conflict with pereira et al 2023. RC percentage was 80.83%, 87.9% and 66.67 %, 44.44 % for both studies respectively. These results may be attributed to different techniques between studies. Pereira et al used modified VISITA technique. It is easier to stabilize SCTG in CAF in desired CEJ position in

contrast to VISITA technique. The placental allograft proven to adhere to tissues which could suggests why it showed higher levels of root coverages. In addition, our study is in agreement with Pradhan et al 2022 and others. (23,25,28)

The overall professional esthetic evaluation according recession esthetic score showed no difference between groups with significant difference through each group. Patient reported outcomes shows revealed a statistically significant disparity regarding morbidity and time to recovery between both groups. Test group demonstrated mean value range 4.0 ± 1.17 in morbidity VAS while control group mean value was 8.5 ± 1.08 . in addition, control group took more days to be able to eat freely. These finding can be attributed to extended surgical time and second surgical site. Overall patient esthetic evaluation ranges illustrated no difference between both groups. These findings are consistent with Pradhan et al 2022. (23)

The improvement in all clinical parameters could be attributed to biological properties of placental allograft. The ample amounts of cytokines, angiogenic factors and stem cells, that characterize this allograft, which are responsible for rapid wound healing, tissue regeneration, and root coverage.

recommendations

Extended follow-up periods are necessary to evaluate the long-term stability of the clinical outcomes. Employing a split-mouth design would enhance the generalizability of the findings.

CONCLUSION

The combination of ACM with CAF demonstrated a viable option for treating RT1. When comparing the test group to control group no difference was found. This suggests using ACM as a substitute for SCTG to avoid the limitations associated with harvesting a SCTG.

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Conflicting Interest nil

Source(s) of support: none.

Ethical policy and Institutional Review Board statement:

The study was conducted in accordance with the International Conference on Harmonization Good Clinical Practice (ICH-GCP) guidelines, the ethical principles outlined in the Declaration of Helsinki, and was approved by the Research Ethics Committee of the Faculty of Dentistry, Minia University which approved research proposal at its 101-committee

meeting with decision number 857. and it was registered at ClinicalTrial.gov (NCT06508476) and followed the CONSORT statement (<http://www.consort-statement.org/>).

Patient declaration of consent statement:

Prior to study enrollment, all participants received a comprehensive explanation of the treatment protocol, encompassing procedural steps, potential risks, and anticipated outcomes. Informed consent was obtained in writing from each patient.

Data Availability statement:

data generated in this present study may be requested from the corresponding author.

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