

## XENOGENEIC ACELLULAR DERMAL MATRIX VERSUS CONNECTIVE TISSUE GRAFT IN CONJUNCTION WITH TUNNELING TECHNIQUE IN TREATMENT OF GINGIVAL RECESSION (RANDOMIZED CONTROLLED CLINICAL TRIAL)

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### *ABSTRACT*

**Objective:** The aim of the present study was to compare the use of Xenogeneic Acellular Dermal Matrix versus connective tissue graft in conjunction with tunneling technique in treatment of gingival recession by esthetic outcome, clinical parameters, and patient satisfaction.

**Materials and methods:** 16 patients of each gender with age vary from 20 to 40 years diagnosed with wither gingival recession Miller class I or class II. The patients were divided randomly into two groups. Group I (test group) were treated with xenogeneic acellular dermal matrix in combination with the tunneling technique. Group II (control group) were treated with connective tissue graft in combination with the tunneling technique. The following clinical parameters were measured at baseline, 3 and 6 months postoperatively: gingival recession depth (GRD) and width (GRW), probing depth (PD), clinical attachment level (CAL), keratinized tissue width (KTW), mean root coverage (MRC), complete root coverage (CRC) and Root Coverage Esthetic Score (RES).

**Results:** 3 and 6 months postoperatively, both groups showed significant improvement in all clinical parameters compared to baseline, with no statistically significant difference between both groups. Connective tissue graft can be slightly superior to the xenogeneic acellular dermal matrix in terms of complete root coverage and esthetic score but with no statistically significant difference.

**Conclusion:** Xenogeneic acellular dermal matrix can be considered as a viable substitute for connective tissue graft due to the marked improvement in all clinical parameters following its use and having the advantage of avoiding the second surgical site and patient morbidity following grafting procedures.

**KEYWORDS:** Gingival recession, Xenogeneic acellular dermal matrix, Connective tissue graft, Tunneling technique,

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## INTRODUCTION

Gingival recession is a common condition usually encountered in our daily practice, and it is one of the various periodontal problems that can give rise to both esthetic & functional complaints. Gingival recession can be defined as the displacement of the gingival margin apical to the cemento-enamel junction (CEJ) of a tooth or the platform of a dental implant.<sup>(1)</sup>

There are various etiological factors that may lead to gingival recession including increasing in age, pathological factors, anatomic factors, physiological factors & iatrogenic factors.<sup>(2)</sup> There are multiple treatment options that were proposed in gingival recession treatment depending on the patient's chief complaint, the treatment can be non-surgical or surgical treatment. Over the years multiple surgical techniques have been proposed for the treatment of gingival recession ranging from the pedicle flaps which included the rotational flaps (laterally positioned flaps & double papilla flap) and the advancement flaps (Coronally positioned graft & semilunar flap) and more recently the tunneling technique.<sup>(3)</sup> These techniques were used with various biologic grafting materials or synthetic materials along with root modification agents. Other techniques were proposed as the guided tissue regeneration usage in gingival recession treatment.<sup>(4)</sup>

The efficacy of tunneling technique in the treatment of gingival recession defects showed comparable results when compared with coronally advancing flap in complete & mean root coverage percentages, keratinized tissue gain & the root coverage esthetic score, with superior esthetics of tunneling technique due to enhanced gingival contour, keloid formation absence and tissue texture all owing to avoiding vertical incisions & keeping the papilla intact. The efficacy of the tunneling technique was enhanced by the addition of various grafting materials.<sup>(5)</sup>

In periodontal plastic surgery, the use of soft tissue grafts has become a substantial element. In

the last 50 years of clinical periodontology and still today soft tissue autografts have characterized the practice.<sup>(6)</sup> *Chambrone and Tatakis in 2015*<sup>(7)</sup> concluded that various grafting materials can be used in the treatment of Miller class I and II gingival recession cases, exhibiting decreased recession depth and increase in keratinized tissue width. The subepithelial connective tissue graft was found to be more superior.

Despite the superiority of the subepithelial connective tissue graft there were certain limitations and complications associated with it. One of the major complications was the patient morbidity associated with the surgical technique, complications such as excessive bleeding at the palate, dysfunction of the palate sensation, infection and/or prolonged surgical time. Another limiting factor is the availability of donor tissue in cases of multiple gingival recession defects. Lastly the requirement for a second surgical site and an increase in surgical time that may be further associated with higher postoperative pain and swelling.<sup>(8-11)</sup>

In searching for alternatives various biomaterials have been introduced and gained popularity owing to their abundance, reducing the surgical time and avoiding a second surgical site. Various materials were proposed such as natural and cadaveric scaffolds (Human amniotic membrane, decellularized human dermis). Xenogeneic collagen matrices were also used (Volume stable collagen matrix, extracellular matrix, bilayered collagen matrix, xenogeneic acellular dermal matrix.). Human growth factors such as platelet concentrates has also been proposed.<sup>(4,12,13)</sup>

Porcine derived acellular dermal matrix (PADM) is a collagen matrix originating from a multi-step process resulting in the removal of antigenic components from porcine dermis. It acts as a scaffold for the proliferating fibroblasts and endothelial cells allowing for the vascularization of its structure where periodontal regeneration was observed in

histological assessment. <sup>(4)</sup> PADM can be used in the treatment of gingival recession as it shows complete incorporation into the adjacent gingival tissues without affecting the healing process, with the collagen membrane having greater soft tissue thickness & soft tissue height when compared to enamel matrix derivative which indicate that it may in root coverage treatment increase and maintain the volume of soft tissue. <sup>(14)</sup>

Therefore, the aim of this study was to assess the efficacy of the xenogeneic acellular dermal matrix and the connective tissue graft when combined with the tunneling technique in the treatment of Miller class I & II gingival recession defects, where the primary objective was to assess the effects of both grafts clinically and esthetically as a treatment modality.

## SUBJECT AND METHODS

### Study design & sample size calculation

This is a Randomized controlled clinical trial. A power analysis was done to have adequate power to apply a two-sided statistical test of the null hypothesis that there is no difference in amount of root coverage between Xenogeneic Acellular Dermal Matrix and connective tissue graft in conjunction with tunneling technique in treatment of gingival recession. By adopting an alpha level of (0.05), a beta of (0.2) i.e., power=80% and an effect size (h) of (1.41) calculated based on the results of *Gurlek et al. (2019)* <sup>(15)</sup>; the predicted sample size (n) was a total of (16) cases (i.e., 8 cases per group).

16 patients participated in this clinical trial who were diagnosed with Miller class I & II gingival recession. The recruiting of the patients was done from the Oral Medicine, Periodontology, Oral Diagnosis and Radiology Department outpatient clinic at the faculty of Dentistry, Ain Shams University. All the patients were informed with the

purpose of this study and before the conduction of the study an informed consent was signed. The proposal was proposed to the Research Ethics committee at faculty of Dentistry Ain Shams University and was approved before starting the research (FDASU-Rec IM 111803).

The participants were included or excluded according to the following criteria: Inclusion criteria: Both genders aged between 20-40 years. Patients diagnosed with multiple Miller class I or II in anterior and premolar teeth (Class I: Marginal tissue recession, which does not extend to the mucogingival junction (MGJ), there is no periodontal loss (bone or soft tissue) in the interdental area, and 100% root coverage can be anticipated, class II: Marginal tissue recession, which extends to or beyond the MGJ, there is no periodontal loss (bone or soft tissue) in the interdental area, and 100% root coverage can be anticipated). No systemic diseases which could influence the outcome of the therapy (**American Society of Anesthesiologists I; ASA I**). Good compliance with the oral hygiene measures following initial therapy and availability for follow up and maintenance program. Exclusion criteria: Patients suffering from active periodontitis, smokers, vulnerable group of patients (prisoners and handicapped), presence of occlusal interferences, pregnant and lactating females, carious teeth and teeth with periapical infection.

Patient grouping, randomization & blinding: Group I (test group): Included eight patients who received Mucoderm (Botiss dental GmbH, Berlin, Germany) with tunneling technique for the treatment of gingival recession. Group II (study group): Included eight patients who received Sub-epithelial connective tissue graft with tunneling technique for the treatment of gingival recession. Computer generated randomization ([www.randomizer.org](http://www.randomizer.org)) was used to randomly allocate the patients into both groups. Allocation concealment was done using a coded opaque sealed envelope containing

the subject's treatment of option. A separate and blinded operator scored and evaluated the clinical and esthetic parameters at 3 and 6 months postoperatively.

#### **Treatment Protocol:**

Pre surgical phase: Full conventional periodontal treatment including supra-gingival scaling and sub-gingival periodontal debridement were performed using ultrasonic scaler, hand scalers and curettes. Oral hygiene instructions were stressed repeatedly until an adequate level of oral hygiene was achieved by the patients (brushing twice daily and dental flossing) and after two weeks there was a recall visit for the patient to record the base line clinical parameters readings as shown in figures (1a & 1b).

For the selected sites, the assessment of the following clinical parameters was done at baseline, 3 and 6 months after the surgical procedure using periodontal probe (UNC-15): Plaque index (PI), bleeding index, probing depth (PD), clinical attachment level (CAL), gingival recession depth (GRD), gingival recession width (GRW), keratinized tissue width (KTW), complete root coverage (CRC) and mean root coverage (MRC).

Surgical phase: Anesthesia was administered at the recession area, intrasulcular incisions were made with a surgical blade (15C) on the buccal aspect of

the involved teeth. The mucoperiosteal flap was raised using tunneling knives (Tunneling Knives, Hu-Friedy). A split flap was performed by extending the tunnel beyond the mucogingival junction and under each papilla, so complete coronal tension-free advancement can be allowed.<sup>(16)</sup> Mattress sutures were used to pull the graft into the prepared tunnel and fixed mesially and distally. Finally, the tunnel was advanced coronal to the cemento-enamel junction by means of suspended sutures using 5.0 non absorbable polypropylene sutures (Assut Sutures, Switzerland) on the tooth surface which is briefly etched, thoroughly washed and dried by flowable composite in order to completely cover the graft and preventing effectively apical relapse of the gingival margin during early stages of healing.<sup>(17)</sup> The test site was treated by PADM (Mucoderm, Botiss dental GmbH, Berlin, Germany) 30x40 membrane which was cut to the required size and then soaked in saline for 20 mins following the manufacturer's instructions and then pulled into the tunnel and sutured in place as shown in figure (3). The control group was treated by means of connective tissue graft, where a free gingival graft was harvested and de-epithelialized outside the oral cavity to be utilized as connective tissue graft<sup>(18)</sup> which was then pulled into the prepared tunnel and sutured in place with the flap being advanced.

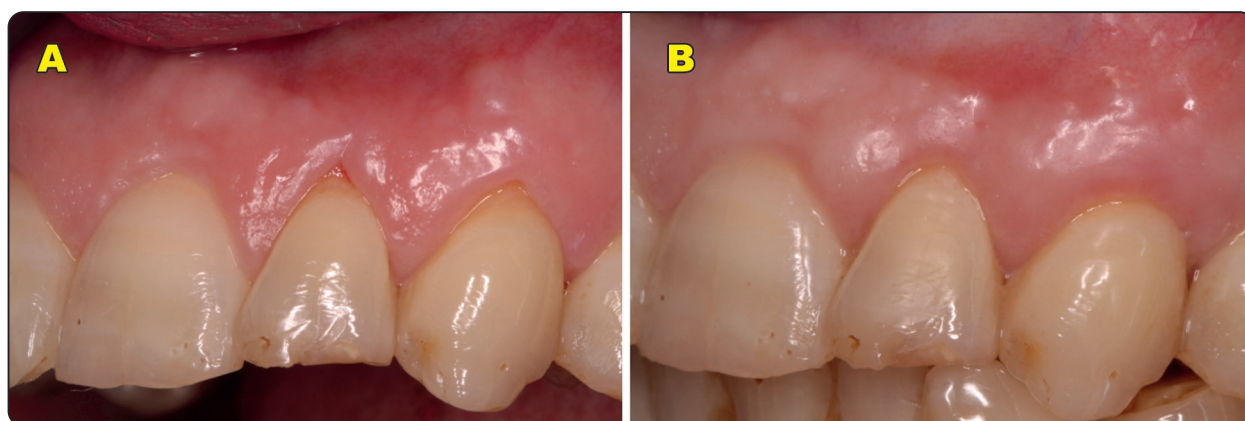


Fig. (1) (a): Test site prior to treatment, (b): 6-months outcome



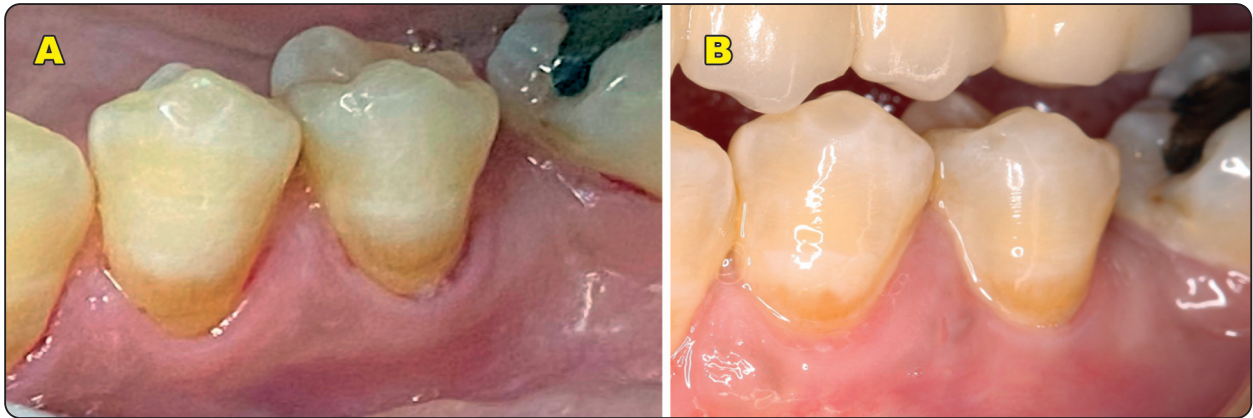


Fig. (2) (A): Control site prior to treatment, (B): 6-moths outcome

### Postoperative care:

Patients were instructed to take antibiotics twice daily for one week (Augmentin, 1gm, GlaxoSmithKline, Cairo, Egypt), and (Brufen, 600mg, Abbott laboratories, Cairo, Egypt) to be taken when necessary. Brushing at the surgical site was to be avoided by the patients. The patients were told to rinse twice daily with chlorhexidine mouthwash (Hexitol, The Arab Drug Company, Cairo, Egypt). Sutures were removed after 2 weeks. Postoperative care, which included the reinforcement of oral hygiene measures and whenever necessary during the recalls mechanical plaque removal was performed.

### Postoperative evaluation & Assessment:

Recall appointments were scheduled for the patients every month for 6 months to examine the surgical area and for remove plaque when required. A separate and blinded operator scored and evaluated the clinical and esthetic parameters at 3 and 6 months postoperatively. The Root coverage esthetic score (RES) system by *Cairo et al. 2009*.<sup>(19)</sup> was utilized as the esthetic outcome evaluation method. Patients were asked if they were satisfied with the appearance of the operated site, and if they would undergo the same surgery again as shown in figures (1b & 2b).



Fig. (3) : Intraoperative view

### Statistical Analysis:

Categorical data were presented as frequency and percentage values and were analyzed using Fisher's exact test for intergroup comparisons and Cochran q test followed by pairwise comparisons utilizing multiple McNemar's tests with Bonferroni correction for intragroup comparisons. Numerical data were presented as mean and standard deviation values and were explored for normality by checking the data distribution, calculating the mean and median values and using Kolmogorov-Smirnov and Shapiro-Wilk tests. Parametric data were analyzed using independent t-test and repeated measures ANOVA followed by Bonferroni post hoc test for inter and intragroup comparisons respectively.

While non-parametric data were analyzed using Mann Whitney U and Freidman's test followed by Nemenyi hoc test for inter and intragroup comparisons respectively. The significance level was set at  $p < 0.05$  within all tests. Statistical analysis was performed with R statistical analysis software version 4.1.3 for Windows.

## RESULTS

Demographic data: The study was conducted on 16 cases that were randomly and equally allocated to both tested groups (i.e., 8 cases per group). There was 4 (50.0%) males and females in the intervention group. While in the control group there was 3 (37.5%) males and 5 (62.5%) females. The mean age in the intervention group was  $(33.12 \pm 1.46)$  years, while in the control group it was  $(32.38 \pm 2.50)$  years. There was no significant difference between both groups regarding sex ( $p=1$ ) and age ( $p=0.476$ ).

Both groups showed no statistically significant difference in any clinical parameters recorded at the baseline conditions, all assessed parameters were significantly improved when compared to baseline, regardless of the treatment modality as shown in table (1). At the 6 months post-operative examination, there was no statistically significant difference regarding the PD measurement when compared with baseline measurements showing slight change. There was significant CAL gain reducing from  $(3.12 \pm 0.64)$  mm to  $(1.75 \pm 1.49)$  mm in the test group and from  $(3.62 \pm 1.60)$  mm to  $(1.75 \pm 1.39)$  mm at the control group at 6 months. GRD showed statistically significant reduction on both sides ranging from  $(1.75 \pm 0.46)$  mm to  $(0.62 \pm 0.74)$  mm on the test group side and from  $(2.38 \pm 1.30)$  mm to  $(0.75 \pm 1.16)$  mm on the control group side. GRW also showed a reduction from  $(2.38 \pm 0.52)$  mm to  $(0.88 \pm 1.13)$  mm in the test group and from  $(2.12 \pm 0.83)$  mm to  $(1.00 \pm 1.51)$  mm in the control group.

TABLE (1): Mean, Standard deviation (SD) values for the intergroup comparison of clinical parameters

Parameter	Time	Clinical parameters		p-value
		(Mean $\pm$ SD)		
		Intervention	Control	
PD	Baseline	1.38 $\pm$ 0.52	1.25 $\pm$ 0.46	<b>0.619ns</b>
	3 months	1.32 $\pm$ 0.36	1.20 $\pm$ 0.46	<b>0.113ns</b>
	6 months	1.29 $\pm$ 0.48	1.12 $\pm$ 0.35	<b>0.278ns</b>
CAL	Baseline	3.12 $\pm$ 0.64	3.62 $\pm$ 1.60	<b>0.425ns</b>
	3 months	1.62 $\pm$ 1.51	2.00 $\pm$ 1.60	<b>0.637ns</b>
	6 months	1.75 $\pm$ 1.49	1.75 $\pm$ 1.39	<b>1ns</b>
GRD	Baseline	1.75 $\pm$ 0.46	2.38 $\pm$ 1.30	<b>0.222ns</b>
	3 months	0.50 $\pm$ 0.76	0.88 $\pm$ 1.13	<b>0.447ns</b>
	6 months	0.62 $\pm$ 0.74	0.75 $\pm$ 1.16	<b>0.802ns</b>
GRW	Baseline	2.38 $\pm$ 0.52	2.12 $\pm$ 0.83	<b>0.483ns</b>
	3 months	0.75 $\pm$ 1.16	1.25 $\pm$ 1.49	<b>0.467ns</b>
	6 months	0.88 $\pm$ 1.13	1.00 $\pm$ 1.51	<b>0.854ns</b>
KTW	Baseline	4.00 $\pm$ 1.41	2.88 $\pm$ 0.64	<b>0.195ns</b>
	3 months	5.20 $\pm$ 1.30	3.62 $\pm$ 0.52	<b>0.035*</b>
	6 months	5.20 $\pm$ 1.30	3.62 $\pm$ 0.52	<b>0.035*</b>

\*; significant ( $p \leq 0.05$ ) ns; non-significant ( $p > 0.05$ )

Significant increase was encountered in the KTW in the post-operative assessment with an increase from  $(4.00 \pm 1.41)$  mm to  $(5.20 \pm 1.30)$  mm in the test group and from  $(2.88 \pm 0.64)$  mm to  $(3.62 \pm 0.52)$  mm in the control group at 6 months.

Mean root coverage (MRC) was  $(62.50 \pm 44.32)$  % on the test side and  $(73.75 \pm 38.89)$  % on the Control side. Complete root coverage (CRC) was achieved in (50.0%) of the cases in the test group and (62.5%) of the cases in the control group, with significant difference encountered in both groups when compared with the baseline conditions as shown in figure (4). There was a statistically significant difference with marked improvement in the RES parameters in both groups where the average RES in the test group was  $(7.88 \pm 2.10)$  and  $(8.50 \pm 1.60)$  for the control group with no significant difference between both groups.

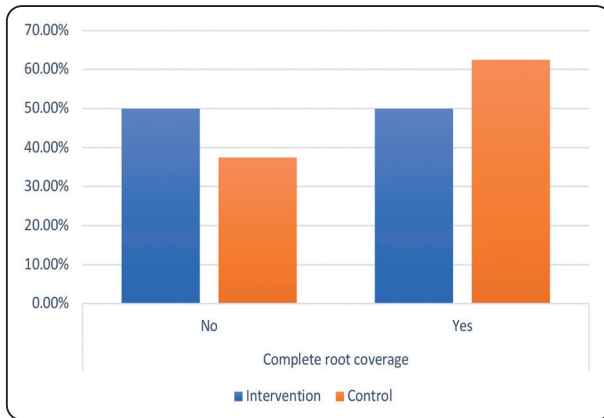


Fig. (4) : Bar chart showing percentage values for root coverage

## DISCUSSION

The aim of the study was to assess the clinical efficacy of the xenogeneic acellular dermal matrix and connective tissue graft in the treatment of gingival recession when used in conjunction with tunneling technique, the results of the study showed significant statistical difference and clinical improvement in all clinical parameters when compared to baseline in both treatment options.

All the clinical parameters showed improvement when compared with baseline conditions, the results of the study concerning the clinical attachment level showed a decrease in this parameter in both the test group and the control group which were in accordance with the results of *Gürlek et al.*<sup>(15)</sup> where they compared xenogeneic acellular dermal matrix with connective tissue graft in conjunction with coronally advanced flap in the treatment of gingival recession, they showed a decrease in CAL in both groups decreasing from  $(4.40 \pm 1.10 \text{ mm})$  to  $(0.56 \pm 1.20 \text{ mm})$  in the CM group and a decrease from  $(4.40 \pm 1.10 \text{ mm})$  to  $(0.39 \pm 0.83 \text{ mm})$  in the CTG group showing improvement in both groups. The results are also in accordance with *Pietruska et al.*<sup>(20)</sup> where they showed a decrease in CAL in both the test and control group with a change from  $(3.52 \text{ mm CTG}; 3.43 \text{ mm PADM})$  to  $(1.98 \text{ mm CTG};$

$2.33 \text{ mm PADM})$  showing an improvement in this parameter.

Marked improvement was also encountered for both the GRD and GRW with values measured at baseline being significantly higher than values of other intervals, the results of the study in regards to recession depth were consistent with the findings of *Cieslik-Wegemund et al.*<sup>(21)</sup> where they compared a collagen matrix and connective tissue graft with tunneling technique in the treatment of gingival recession, there was a marked decrease in the recession depth values where there was a decrease from  $(2.7 \pm 0.9)$  to  $(0.2 \pm 0.4)$  in the control group and a decrease from  $(3.0 \pm 0.8)$  to  $(0.4 \pm 0.3)$  in the test group, showing that both grafts were successful in reducing the recession depth following surgical treatment compared with baseline measurements, the results were also in accordance with the results of *Aroca et al.*<sup>(22)</sup> who compared CTG with collagen matrix using MCAT showing no significant increase between both groups with marked decrease in this parameter after 12 months decreasing from  $(1.9 \pm 0.6 \text{ mm})$  to  $(0.6 \pm 0.5 \text{ mm})$  in the test group and from  $(1.8 \pm 0.5)$  to  $(0.2 \pm 0.3)$  in the control group.

The results of the study regarding mean root coverage (MRC) showed that there was no statistically significant difference between both groups at different intervals with more value of (MRC) achieved in the control group at 6 months. The results of our study regarding mean root coverage (MRC) were comparable with those of *Cieslik-Wegemund et al.*<sup>(21)</sup> who found comparable results between the two groups with the CTG slightly better showing average root coverage (ARC) of (95% CTG; 91% PADM). Another study by *Aroca et al.*<sup>(22)</sup> in 2013 comparing CTG with CM in the treatment of gingival recession using MCAT showing better MRC for the control group over the test group (90% CTG; 71% CM). *Rakasevic et al.*<sup>(23)</sup> found similar results between the CTG & CM upon comparison showing an MRC of (84.6% CTG; 86.9% PADM).

The results of this study concerning CRC showed no statistically significant difference between both groups at different intervals with more value of (CRC) achieved in the control group at 6 months. The results of this study concerning CRC are in agreement with *Rakasevic et al.* <sup>(23)</sup> who compared the use of a similar collagen porcine dermal matrix and connective tissue graft with tunneling technique in the treatment in gingival recession defects, which showed at 6 months CRC of (59.7% PADM; 61.5% CTG) showing comparable results between both types of grafts. *Vincent-Bugnas et al.* <sup>(16)</sup> used the modified coronally advance tunnel technique in conjunction with xenogeneic acellular dermal matrix in treatment of gingival recession defects which showed CRC of (43.32%) after 12 months follow-up period. *Cosgarea et al.* <sup>(24)</sup> evaluated the use of PADM in the treatment of gingival recession in conjunction with MCAT showing CRC of (40.74%) which is slightly lower than the present study but may be owing to the inclusion of *Miller* class III gingival recession defects which have worse prognosis.

The results of the study concerning CRC were not in accordance with the results of *Pietruska et al.* <sup>(20)</sup> concerning the PADM showing CRC of (20%) which could be owing to the study being concerned with gingival recession in the mandible which in more complex with a less favorable anatomy causing improper dimensional stability and vascularization, along with lip muscle pull and minor vestibular depth to coronally mobilize and stabilize the tissues.

The study results concerning keratinized tissue width (KTW) showed that for both groups, at baseline there was no significant difference between both groups while for the other time intervals the test group showed significantly higher values than the control group. The results also showed that for both groups, there was a significant difference between values measured at different intervals with value measured at baseline being significantly lower than values of other intervals.

The study results were in accordance with *Rakasevic et al.* <sup>(23)</sup> who compared CTG with PADM using the tunneling technique showing significant increase in (KTW) in both groups, the natural tendency of the MGJ to regain its genetically determined position may be the cause of (KTW) increase. The results of the study are also in accordance with a systematic review comparing acellular dermal matrix with connective tissue graft for root coverage, the results of this review and meta-analysis showed a small but statistically significant advantage in terms of KT gains for the ADMG over the CTG. The difference could be related to that the augmentation of both the thickness and width of the keratinized band could be owing to the ability of xenogeneic CTG substitutes replacing the host tissues with the required histological and functional characteristics. <sup>(25-27)</sup>

The results of the study were not in accordance with *Gürlek et al.* <sup>(15)</sup> who upon comparison also showed an increase in both groups in terms of KT gain but with advantage towards the CTG group, the difference in these results may be attributed to the multiple factors such as the origin of the graft material, the flap design which can influence the KT gain following root coverage procedures, they applied the coronally advanced flap rather than the tunneling technique used in this study. The author also used a different harvesting technique for the connective tissue graft.

A success in root coverage procedure is a part of esthetic outcomes assessment and rests on position of the GM coronally in respect to CEJ in conjunction with minimal PD. The study used the RES score to assess the results esthetically with both groups showing high-RES values with no significant differences between both groups. The results of the study were somewhat comparable to those of *Rakasevic et al.* <sup>(23)</sup> where it showed an RES score of ( $8.15 \pm 1.65$  for the PADM;  $7.89 \pm 2.02$  for CTG) the slightly higher result for the PADM



may be due to the higher CRC achieved in this study where the level of gingival margin constitutes 60% of the root esthetic score, while the difference in the CTG group may be due to using a subepithelial connective tissue graft unlike the de-epithelialized connective tissue graft for our study. In the study of *Pietruska et al.* <sup>(20)</sup> they had an RES score of  $(7.11 \pm 1.95$  for PADM;  $8.36 \pm 1.78$  for CTG) the lower RES score in the test group is probably owing to the lower CRC achieved leading to a lower score of the level of gingival margin.

## CONCLUSION

Within the limitations of this study xenogeneic acellular dermal matrix can be considered as a viable substitute for connective tissue graft to avoid the second surgical site and patient morbidity, as it was capable of producing satisfactory clinical and esthetic results with comparable results with the CTG, although the CTG was slightly superior in terms of CRC & RES but with no significant difference. Both grafts were capable of increasing the gingival thickness.

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**Conflict of interest** the authors declare that they have no conflicts of interest in this study.

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