Efficacy of Acellular Dermal Matrix Versus Free Gingival Graft for Increasing the Width of Attached Gingiva: A Clinical Trial

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Abstract

Free gingival graft is the gold standard to increase the width of keratinized gingiva. Acellular dermal matrix is a suggested alternative to FGG. This study sought to compare the efficacy of ADM and FGG to increase the width of keratinized gingiva. This randomized controlled clinical trial was conducted on 16 patients with width of attached gingiva ≤1mm. The patients were divided into two groups (n = 8) for treatment with CenoDerm ADM and FGG to increase the width of keratinized gingiva. Clinical parameters including the plaque index, gingival index, probing depth and width of attached gingiva were assessed and compared between the two groups immediately after surgery and at three months. The data were analyzed using SPSS version 22 via paired t-test and Mann Whitney U test. The increase in width of attached gingiva was significant in both groups at three months compared to baseline (both Ps = 0.001). The mean increase in width of attached gingiva was 2.42±0.9mm in the test and 4.25±0.7mm in the control group; this difference was statistically significant (P = 0.001). The mean graft shrinkage was 68.9±10.9% in the test and 42.75 ± 12.81% in the control group; this difference was statistically significant as well (P = 0.001). However, both techniques yielded clinically acceptable results.

Introduction

Adequate width of keratinized gingiva is required for periodontal health and prevention of progressive recession of connective tissue attachments.[1,2] Inadequate width of attached gingiva cannot protect the periodontium against friction traumas nor can it resist tensile forces applied by the underlying muscles to the gingival margin.[2] Inadequate width of keratinized gingiva prevents healing of periodontal pockets due to the movement of marginal tissue and leads to accumulation of sub-gingival plaque, which results in attachment loss and gingival recession.[3] Biologically, "adequate width of attached gingiva" refers to a width of keratinized gingiva (including free gingiva and attached gingiva) that prevents movement of gingival margin during the movements of alveolar mucosa and maintains gingival health.[4] This value has been reported to be in the range of 1-3mm.[5]

Several methods have been proposed to increase the width of attached gingiva, which primarily included periosteal retention and denudation surgeries and their modifications. However, the afore-mentioned techniques were commonly associated with unpredictable results, postoperative complications and pain and did not have optimal efficacy.[6, 7] Thus, the graft technique was introduced to overcome such shortcomings.

Free gingival graft was first introduced in 1963 by Bjorn[8] and since then, it has been extensively applied to increase the width of attached gingiva with successful results. It remains to be the gold standard technique for increasing the width of keratinized gingiva. However, this method has some drawbacks as well including the need for a donor site (second surgical site) to harvest the graft, anatomical

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limitations and color and texture mismatch between the graft and the recipient site. Therefore, researchers have been in search of efficient alternatives to overcome these limitations.[9, 10]

Acellular dermal matrix was first used in 1992 for treatment of burns[11] and was later successfully used for treatment of mucogingival defects.[12-14] This allograft has shown optimal clinical results when used around teeth and implants.[13] It is derived from human skin (from cadavers) via aseptic procedures. In this process, epidermis and cellular components of dermis are eliminated while the basement membrane and extracellular matrix are preserved. This allograft serves as a scaffold for migration of fibroblasts and vascularization initiated in the adjacent tissues. By elimination of cells from ADM allografts, the possibility of unfavorable immunological reactions such as graft rejection and transmission of pathogenic viruses is non-existent.[15] Acellular dermal matrix is used for root coverage and reconstruction of soft tissue and alveolar ridge.[16-18] It has no limitation in amount and eliminates the need for a second surgical site to harvest a graft. However, it has some drawbacks as well including the risk of creeping attachment not happening, healing with connective tissue adhesion and the need for adequate blood supply in order for the graft to unify with the underlying tissue.[19-21]

Successful results of application of ADM for increasing the width of attached gingiva have been reported in children, who required this intervention due to trauma, orthodontic treatment or frenal tension.[22-24] Its application for treatment of peri-implant gingival defects has been successful as well.[25-27] Use of ADM provides optimal width of attached gingiva and acceptable color match.[28-30]

Patients experience less pain and discomfort since a palatal graft is not harvested. Also, use of ADM provides higher esthetics compared to FGG, which is particularly important in the esthetic zone. Considering the above-mentioned advantages, Tissue Regeneration Corporation introduced CenoDerm for applications in gingival reconstruction, flap closure in bone graft surgery, reconstruction of recessed gingiva or biopsy defects, guided bone regeneration and guided tissue regeneration.

Considering the gap of information on the efficacy of CenoDerm ADM for increasing the width of attached gingiva, this study sought to assess and compare the efficacy of treatment with ADM and FGG.

Materials and Methods

This randomized controlled clinical trial was conducted on 16 patients presenting to the Department of Periodontics at School of Dentistry, Qazvin University of Medical Sciences in 2014 with inadequate width of attached gingiva due to periodontal disease, trauma or anatomical variations requiring surgery to increase the width of attached gingiva. The study protocol was approved in the ethics committee of Qazvin University of Medical Sciences (Ethical code: 28/20/10038) and registered in www.irct.ir (IRCTID: IRCT2015051222249N1).

Sample size was calculated to be 16 patients considering 95% confidence interval, standard error of 15% (d = 0.15) and estimated mean prevalence of 10% based on a previous study.[24, 31] Sampling was sequential and targeted until the sample size was reached. The inclusion criteria were: (a) patients capable of maintaining adequate oral hygiene with GI and PI < 1, (b) having at least one tooth with width of attached gingiva ≤ 1 mm with inflammation, pain, discomfort or unaesthetic appearance, (c) probing depth of < 3 mm in the buccal surface of the respective tooth, (d) no systemic disease and (e) no smoking.

Patients who were not able to follow oral hygiene instructions or postoperative care and those who could not show up for the follow-ups were not included.

All phases of the study were conducted in accordance with the declaration of Helsinki.[32] If required, patients underwent phase I periodontal therapy and recalled after two months; those with adequate oral hygiene were recruited. Patients were briefed about both techniques and possible complications and signed written informed consent forms.

For assessment of GI,[33] mesial, buccal, distal and lingual/palatal surfaces of the teeth were examined and scored. Absence of visible inflammation was scored 0, slight change in gingival color and consistency was scored 1, visible inflammation and bleeding on probing was scored 2 and severe inflammation and spon-taneous bleeding was scored 3. The sum of the four values was divided by 4 and reported as GI.

For assessment of PI,[33] four surfaces of mesial, buccal, distal and lingual/palatal of the teeth were examined and scored. Absence of plaque was scored 0, slight plaque detected by probing was scored 1, visible plaque was scored 2 and abundant plaque was scored 3. The sum of all four scores was divided by 4 and reported as PI.

Probing PD was determined by measuring the distance from the gingival margin to the sulcus depth at the mesiodistal mid-point of the buccal surface using a Williams probe (Nordent Manufacturing Inc., IL, USA). The probe was inserted parallel to the long axis of the tooth.

Width of attached gingiva (distance from the sulcus depth to the mucogingival junction) was measured using a periodontal probe. To determine the mucogingival junction, rolling technique was employed. In this technique, mobile mucosa is retracted coronally to determine the keratinized gingiva.

Eight patients with a mean age of 43.5±11.46 years (range 25-65 years) underwent treatment with ADM and eight patients with a mean age of 45.5±8.26 years (range 37-60) were subjected to treatment with FGG. The patients were recalled 14 days later. Dressing was removed and the surgical site was rinsed with 2% chlorhexidine. The sutures were removed. Three months later, clinical parameters (GI, PI, PD) were examined and recorded again for each patient. Width of graft was also recorded for all patients during the surgery. At three months, percentage of changes in graft width was calculated.

Surgical procedure

After prep and drape and administration of infiltration anesthesia with 2% lidocaine and 1:80,000 epinephrine (Invima, Colombia), a horizontal incision was made at the mucogingival junction and a partial thickness flap was elevated by cutting the connective tissue and muscle attachments to the underlying periosteum. In case of movement, flap margins were fixed to the vestibular depth using 4-0 chromic gut sutures (Supa, Tehran, Iran). Areas coronal to the primary incision were de-epithelialized (Figure 1).

Figure 1. An Incision was Made at the Mucogingival Junction; A Partial Thickness Flap was Elevated, and Coronal Areas were De-Epithelialized (Both Test and Control Groups) (B) ADM (CenoDerm) was Fixed in Place with Sutures (Test Group).

A

B

Figure 2. (A) Harvesting a FGG from the Hard Palate (Control Group) (B) FGG was Fixed in the Recipient Site with Sutures (Control Group).

In the test group, ADM (CenoDerm; Tissue Regeneration Corporation, Kish, Iran) was used measuring 1 × 2 cm with > 1.5mm thickness. It was immersed in sterile saline for 10 minutes according to the manufacturer's instructions, adjusted to match the shape of the recipient site and placed on the periosteum. The ADM was placed at the recipient site in such a way that basement membrane was towards the vestibule and connective tissue was adjacent to

the periosteum. It was then sutured with 5-0 silk sutures (Supa, Tehran, Iran). Fixation was done with simple interrupted sutures in coronal and lateral borders and suspensory periosteal sutures (Figure 2).

In the control group, a FGG was harvested from the hard palate using a #15 scalpel (Figure 3). The minimum thickness of the graft was 1-1.5mm. The clot at the donor site was stabilized using 4-0 silk sutures (Supa, Tehran, Iran). The recipient site was covered with the keratinized graft (1-1.5mm thickness) and sutured with 5-0 sutures as in the test group (Figure 2B).

A

B

Figure 3. Three-month Postoperative Photographs (A) ADM (B) FGG.

The recipient side in both groups and the donor site (hard palate) in the control group were temporarily dressed with periodontal dressing (Coe-Pak, GC America Inc., Alsip, IL, USA). Post-operative instructions for all patients included 500mg amoxicillin three times a day for 10 days and 400mg Gelophen four times a day for five days; 0.2% chlorhexidine mouthwash was also prescribed twice a day for 10 days (Behsa,

Tehran, Iran). Figure 3 shows three-month postoperative photographs of the two groups.

Statistical analysis

The data were analyzed using SPSS version 22 (SPSS Inc., Chicago, IL, USA) via paired t-test and Mann Whitney U test. Level of significance was set at $P < 0.05$.

Results

A total of eight areas in eight patients with a mean age of 45.5 ± 8.26 years (range 37 - 60 years) received FGGs and 12 areas in eight patients with a mean age of 43.5 ± 11.46 years (range 25 - 65 years) received ADM (CenoDerm) to increase the width of attached gingiva. Soft tissue healing in all patients was uneventful and only a few patients complained of mild pain or slight swelling. All patients were females in the test group while there were six females and two males in the control group. The two groups were not significantly different in terms of periodontal parameters at baseline.

The PI, GI and PD values at baseline and at three months in the test and control groups and the respective P values are presented in Tables 1 and 2, respectively. No significant change was noted in PI or GI at three months compared to baseline in any of the two groups; only PD decreased in the test (CenoDerm) group at three months compared to baseline ($P = 0.007$).

The width of attached gingiva at baseline and at three months post-operatively in the test and control groups is presented in Tables 3 and 4, respectively. A significant increase in width of attached gingiva was noted at three months in both groups ($P < 0.001$); the difference in this regard between the two groups was also significant at three months and the width of attached gingiva was significantly greater in FGG group compared to ADM group (P = 0.001). The mean increase in width of attached gingiva was significantly greater in the FGG group compared to ADM at three months ($P = 0.001$). The percentage of graft shrinkage at three months was significantly higher in ADM group compared to FGG group ($P = 0.001$). The difference in graft width at three months was not significant between the two groups ($P = 0.263$).

Parameter	Three months	Baseline	Statistical significance
Probing depth	1 ± 0.0	1.5 ± 0.5	0.007
Plaque index	0.9 ± 0.8	1.5 ± 1.0	0.090
Gingival index	0.16 ± 0.4	0.40 ± 0.5	0.211

Table 1. Periodontal Parameters in the Test Group (CenoDerm) at Baseline and at Three Months.

No significant difference was noted between the test and control groups in PI (P = 0.533), GI (P = 0.477) or PD (P = 1.00) at three months.

Parameter	Three months	Baseline	Statistical significance
Probing depth	1 ± 0.0	1.38± 0.5	0.080
Plaque index	1.06 ± 0.6	1.12 ± 0.6	0.838
Gingival index	0.15 ± 0.75	0.62 ± 0.75	0.074

Table 2. Periodontal Parameters in the Control Group (FGG) at Baseline and at Three Months.

Parameter	ADM (CenoDerm)		Statistical significance
Width of attached gingiva (mm)	Three months	Baseline	0.000
	2.58 ± 0.9	0.17 ± 0.39	
Increase in width of attached gingiva	2.42± 0.9		-
Graft shrinkage (%)	68.9 ± 10.9		-
Graft width (mm)	8.42 ±.99		-

Table 3. The Mean Width of Attached Gingiva and its Changes in ADM Group.

Parameter	FGG		Statistical significance
Width of attached gingiva (mm)	Three months	Baseline	
	4.38 ± 0.744	0.12 ± 0.35	0.000
Increase in width of attached gingiva	4.25 ± 0.7		-
Graft shrinkage (%)	42.75 ± 12.81		-
Graft width (mm)	7.88 ± 1.45		-

Table 4. The Mean Width of Attached Gingiva and its Changes in FGG Group.

Discussion

Absence of attached gingiva significantly compromises periodontal health[2] while presence of as low as 1mm of attached gingiva can maintain periodontal health.[5] The optimal and predictable results of FGGs have been well documented.[34] However, FGGs have drawbacks such as limited availability, donor site morbidity and color and texture mismatch; thus, researchers have been in search of efficient alternatives for this purpose.[9, 10]

Application of ADM for root coverage, guided tissue regeneration, socket preservation and increasing the width of attached gingiva around teeth and implants has been reported with promising results.[21-23] Use of ADM has several advantages including no need for a second surgical site for graft harvesting and subsequently less pain and discomfort of the patient, shorter duration of surgery and favorable esthetic results.[35] In the current study, significant increase in width of attached gingiva was noted at three months in both groups; however, the increase in attached gingiva was significantly greater in FGG group. Although graft shrinkage was also significantly greater in CenoDerm group, the increase in attached gingiva in both groups was clinically acceptable and served the purpose in terms of maintaining periodontal health.

Search of the literature yielded only one study on CenoDerm,[36] and no controlled clinical trial was found for the purpose of comparison. However, ADM manufactured by different companies has been used in many studies. Wei et al, in 2002 compared the outcome of treatment with ADM and FGG[24] and reported a significant increase in width of attached gingiva at six months. Despite the use of wider grafts in ADM group, the increase in width of attached gingiva was smaller and graft shrinkage was greater in this group; which were in line with our findings; they concluded that ADM was less efficient than FGG and the results of treatment with ADM were less predictable (due to higher graft shrinkage). Vieira et al, in 2009 used ADM to increase the width of attached gingiva.[14] They reported 90.43% shrinkage at 90 days, which was higher than the value in the current study; this difference may be due to the fact that they assessed the changes in graft surface and included the horizontal changes in graft dimensions as well.

The magnitude of increase in width of attached gingiva in the current study was in agreement with that reported by Scarano et al, in 2009, who also used ADM in patients with mucogingival defects.[13] The final width of attached gingiva at three months was reported to

be 2mm in their study. Basegmez et al.[21] compared the efficacy of FGG and ADM to increase the width of attached gingiva around implants. The increase in width of attached gingiva was greater in FGG group at both three and six months. Also, relapse of PI and GI had a higher frequency in ADM group. Despite the significant difference in width of attached gingiva at six months between the two groups, this difference was not clinically important because evidence shows that a specific width of attached gingiva is not necessarily required for periodontal health in all patients and the clinical signs and symptoms of patients determine the need for surgical intervention.[4] Scarano et al.,[13] in their study did not report the baseline values while these values can significantly affect the final results. Moreover, they did not use periodontal dressing for wound protection, which could have also affected the results.

Liu et al. used ADM and a resin splint to increase the width of attached gingiva around implants.[37] They gained 6.25mm of attached gingiva at one month, which was highly favorable and greater than our obtained value. However, longer follow ups were not performed while graft shrinkage occurs within three months and longer follow ups could have revealed different results. Moreover, use of resin splint for three weeks might have affected the results. Agarwal et al. reported results similar to ours.[35] They reported 75% shrinkage of ADM after nine months and stated that despite this amount of shrinkage, the obtained width of attached gingiva (2.5mm) was clinically sufficient for periodontal health. Karring et al.[6] discussed that only the connective tissue was able to induce keratinization of epithelial tissue, and the connective tissue genetics dictate the properties of the forming epithelium. In the current study, CenoDerm was placed on non-keratinized tissue while FGG is harvested from the keratinized tissue of the palate and thus, it would have the same properties at the recipient site. Furthermore, it has been reported that the tissue formed by use of ADM is similar to scar tissue;[25] this can justify the greater graft shrinkage in ADM compared to FGG.

The current results showed that ADM yielded clinically acceptable results and can be a suitable alternative to FGG with no complications. The periodontal parameters at three months were not significantly different between the two groups. The PD at three months significantly improved in CenoDerm group; however, it was only statistically, and not clinically, significant since both values were within the clinically acceptable range for periodontal health.

One clinical issue worth noticing was the delay in healing following the use of CenoDerm witnessed by the authors in the current study. However, the final esthetic results (in terms of color and texture match with the adjacent tissue) were significantly superior and more favorable than those in FGG group. Silverstein et al, also reported optimal color match and contour following the use of ADM.[23]

In the current study, level of pain and discomfort of patients was not measured postoperatively. Future studies are required to compare the level of pain between the two groups by use of visual analog scale. Assessments of the course of healing, esthetic results and the effect of thickness of adjacent tissues on the results are also recommended. Moreover, future studies on the thickness of ADM may yield interesting results.

Conclusion

However, due to problems, we only recruited 16 patient and 20 area, within the limitations of this study, the results showed significantly greater graft shrinkage in ADM compared to FGG. However, both techniques yielded clinically acceptable results in terms of periodontal health. Thus, ADM is recommended for use in cases with large defects as well as in patients who cannot physically or mentally tolerate the graft harvesting surgery or when the available tissue for harvesting is not adequate. Furthermore, use of ADM is preferred in the esthetic zone due to its highly favorable esthetic results.

Conflict of Interest

The authors declare that there is no conflict of interest regarding the publication of this article.

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