A Comparative Study of Root Coverage Using Two Different Acellular Dermal Matrix Products

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Background: Gingival recession remains an important problem in dental esthetics. A new dermal matrix material has been introduced, but its effectiveness has not been studied and compared to current dermal matrix material. The aim of this study is to compare the healing associated with a coronally advanced flap for root coverage in areas of localized tissue recession when using Alloderm (ADM) and Puros Dermis (PDM).

Methods: A split-mouth design was used for this study, with 52 contralateral sites in 14 patients with Miller Class I or III facial tissue recession. Twenty-six sites were treated with coronally advanced flap using PDM, and 26 sites were treated with coronally advanced flap using ADM, all followed for 6 months. Clinical measurements of vertical recession, keratinized tissue, probing depths, and attachment levels were made initially, at 3 months, and at 6 months.

Results: Both groups had significant improvement in the amount of recession coverage with means of 2.83 mm for the PDM and 3.13 mm for the ADM. The percentage of root coverage was 81.4% for the PDM and 83.4% for the ADM; differences between the materials were not statistically significant.

Conclusions: Based on the results of this study, there was no statistical or clinical difference in the amount of root coverage, probing depth, or keratinized tissue in coronally advanced flaps for root coverage with either of the two acellular dermal matrix materials. Both materials were successful in achieving root coverage. *J Periodontol 2010;81:1596-1603.*

KEY WORDS

Gingiva; gingival recession; periodontium; surgical flaps; tissue grafts; tooth root.

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The American Academy of Periodontology[1] has defined marginal tissue recession as an acquired deformity with the gingival margin being located apical to the cemento-enamel junction (CEJ), resulting in exposed root surface and loss of attached gingiva. A variety of surgical techniques has been developed to attain root coverage, including free gingival graft (FGG),[2,3] sliding flaps,[4,5] double papilla grafts,[6] connective tissue grafts (CTGs),[7] coronally positioned flaps,[8,9] coronal positioning of previously placed FGG,[10,11] and guided tissue regeneration.[12-14] The predictability of these procedures has improved with modifications, such as the coronally advanced flap (CAF) combined with a soft tissue graft. The objective of these modifications is to enhance blood supply to the graft, thereby resulting in increased success rates. Many surgical techniques have been evaluated to achieve more effective and predictable root recession coverage, especially in multiple adjacent sites. Zucchelli and De Sanctis[15] evaluated the effectiveness of a surgical procedure that coronally advanced the flap for treatment of multiple Miller[16] Class I and II recession defects in patients with esthetic demands. Briefly, the horizontal incisions of the envelope flap consist of oblique submarginal incisions interdentally continuous with intrasulcular incisions at the recession defects. At the 1-year examination, mean

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root coverage of 97% was reported. Also, 88% of the sites had complete root coverage, suggesting that without vertical releasing incisions, the blood supply to the flap was adequate, a factor deemed critical to the success of the surgery.

Many authors[17-19] have suggested that the gold standard for root coverage procedures is the subepithelial CTG technique, which requires a donor site and a recipient site, leading to greater patient discomfort and increased surgical time. The need for a second surgical procedure to harvest donor tissue is a disadvantage of the CTG because only a limited amount of donor tissue is available for multiple recession defects. Thus, there has been a desire to find a substitute to replace the autogenous donor tissue.

As a response, acellular dermal matrix graft† (ADM) has been used as a substitute for CTG in root coverage procedures. The ADM allograft is processed to remove the epidermal layer along with all of the dermal cellular structures, thereby removing the factors responsible for graft rejection and infection. The allograft acts as a scaffold for the vascular endothelial cells and fibroblasts to repopulate the connective tissue matrix and encourage the epithelial cells to migrate from the adjacent tissue margins.[20] The healing process observed in the allograft is similar to that seen in autogenous grafts.[21,22] In 2005, a meta-analysis of eight randomly controlled clinical trials showed no statistically significant differences between groups (ADM and CTG) for measured outcomes: recession coverage, keratinized tissue (KT), probing depth (PD), and clinical attachment levels.[23] Others have reported that treatment with ADM was an effective and predictable procedure for root coverage compared to CTG.[24-28] A human histologic case series[29] comparing CTG and ADM grafts with 6-month healing indicated that the gingival attachment to the root surface was comparable in both CTG and ADM. The ADM seemed well incorporated with new fibroblasts, vascular elements, and collagen, while retaining its elastic fibers throughout; it was apparent that equivalent attachment to the root surface was observed between CTG and ADM.

A new material, an allograft tissue matrix‡ (PDM), was introduced as an acellular dermal allograft for root coverage in the treatment of gingival recession. The allograft retains the natural collagen matrix and mechanical properties of native dermis as a result of the company's proprietary Tutoplast process.[30] While preserving the collagen matrix and tissue integrity, this process removes the cellular components. Also, the tissue processing preserves tissue biomechanical properties, while inactivating bacterial, viral, and prion contamination and eliminating antigenicity. The material is packaged in a sterile packet with the absence of residual antibiotics. The cost of the two products is very similar, and rehydration of the PDM is reported by the manufacturer to be only 30 seconds compared to 20 to 30 minutes for ADM. At the time the study was performed, the thickness of the PDM was not reported by the manufacturer, whereas ADM was reported to have a thickness of 0.89 to 1.65 mm. The PDM represents a possible alternative to the use of ADM if it can yield equal or better results in root coverage.

A review of the literature has failed to detect any reports where clinical healing of root coverage with ADM and PDM has been compared. Thus, the aim of this study was to compare the healing associated with CAF for root coverage in areas of localized marginal tissue recession when using ADM and PDM.

MATERIALS AND METHODS

The protocol for this study was approved by the Institutional Review Board of the Texas A&M Health Science Center, Baylor College of Dentistry, Dallas, Texas. Each subject received verbal and written instructions and signed the informed consent form before participating in the study. Subjects were selected based on the following criteria: ≥18 years old; bilateral buccal vertical recession of ≥2 mm depth (measured from the CEJ to the midfacial gingival margin) limited to incisors, canines, and premolars; Miller recession Class I, II, and III; good plaque control defined as a modified O'Leary index[31] of ≥85% plaque free after initial therapy; vital teeth; absence of bleeding on probing at the surgical sites; and PD of ≤2 mm. All subjects were in good health and were not aware of any systemic conditions. All subjects met the inclusion criteria stated previously before enrollment in this study.

Before surgical procedures, all subjects received a prophylaxis and scaling if needed, and oral hygiene instructions consisting of flossing and brushing using an extra soft toothbrush with a technique starting apically on the gingiva and gently sweeping coronally with the toothbrush. This was done to address the habits that could be related to the gingival recession and to achieve effective plaque control. Localized periapical radiographs were taken to evaluate interproximal alveolar bone level and to assist in gingival recession classification of teeth exhibiting recession defects.

The randomized controlled trial was a split-mouth design in which subjects with bilateral gingival recessions were treated. Treatment was determined by random assignment into two parallel groups to assess equivalence. All measurements were made by the same investigator (FR-H) who was masked as to

† Alloderm, BioHorizons, Birmingham, AL.
‡ Puros Dermis, Zimmer Dental, Carlsbad, CA.

treatment site assignment. A North Carolina periodontal probe was used for tissue measurements to the nearest 0.5 mm. Each subject was treated on one side with CAF combined with ADM, and the contralateral side was treated with CAF combined with PDM at the same appointment. The subjects were selected from patients seeking dental care from August 2007 to May 2008 at Texas A&M Health Science Center, Baylor College of Dentistry.

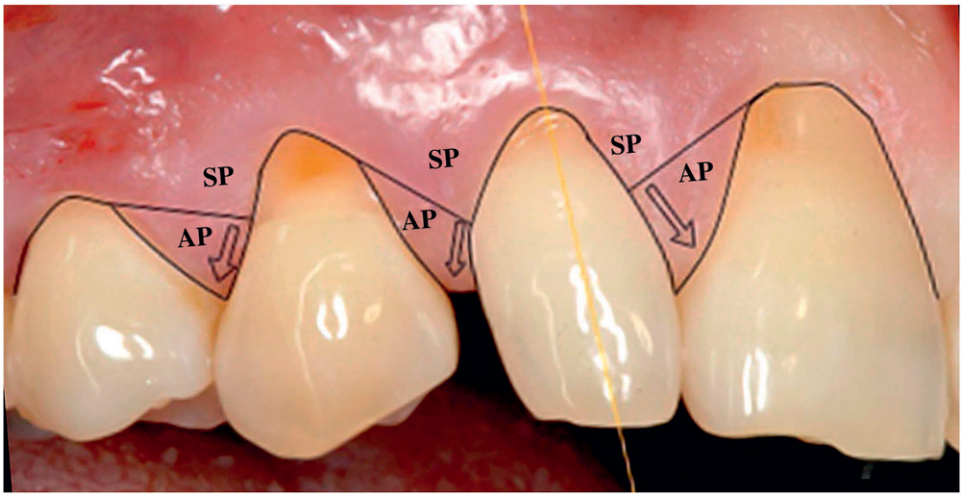

Figure 1.
Zucchelli incision design. SP = surgical papilla; AP = anatomic papilla. Arrows indicate direction of rotation.

The clinical parameters evaluated were as follows: gingival index[32] scored as 0 to 3; presence of bleeding on probing; vertical recession defined as the distance from the CEJ to the free gingival margin on the midfacial aspect; PD, defined as the distance from the free gingival margin to the bottom of the sulcus on the midfacial aspect; probing clinical attachment level, defined as the distance from the CEJ to the end of the probe on the midfacial aspect; the width of the KT, defined as from the free gingival margin to the mucogingival junction on the midfacial aspect using an iodine solution.§ The flap tension was also evaluated and flaps were rendered passive before suturing. Patients were "masked" to the test and control sites, and all surgeries were performed by the principal investigator.

Two additional masked, experienced clinical examiners (MMB, JAR) graded the healing appearance of the surgical sites as "better," "worse," or the "same" as the contralateral site at 1 and 4 weeks based on presence or absence of inflammation, spontaneous bleeding, necrosis, retracted flap, purulence, and history of pain. The patients recorded their pain experience at each surgical site at the 1 week postoperative appointment. Pain was recorded using a visual analog scale 0 to 100 mm, where 0 was no pain and 100 was the worst pain imaginable.

Surgical Procedure

The surgical sites were anesthetized with 2% lidocaine HCl with 1:100,000 epinephrine followed by 0.5% bupivicaine with 1:200,000 epinephrine. The incision design introduced by Zucchelli and De Sanctis[15] (Fig. 1) avoiding vertical incisions was used throughout the study. Full-thickness mucoperiosteal flap reflection was extended to 3 mm apical to the alveolar bone crest using a periosteal elevator, followed by split-thickness flap reflection. Split-thickness flap dissection was extended mesially, distally, and apically to facilitate adequate mobility and coronal positioning of the flap without tension using a number 15 blade.‖ The portion of the root surfaces previously exposed to the oral cavity was thoroughly planed using curets to remove plaque, calculus, and soft tooth structure. Any gross irregularities of the root surface were smoothed using a fine diamond bur and the sites were rinsed with a sterile saline solution. No further root conditioning, mechanical or chemical, was performed. The anatomic papillae were then deepithelialized to ensure the exposure of the connective tissue vascular bed.

Rehydration of the test acellular dermal matrix (PDM) with sterile saline was performed according to the manufacturer's guidelines. The graft was trimmed and adjusted to cover the defect completely and was positioned at the CEJ; whereas the apical and lateral borders of the graft were extended at least 3 mm beyond the alveolar bone margin (Figs. 2C and 2D), the test matrix does not have connective tissue versus basement membrane sides to differentiate. All control (ADM) grafts were oriented with the connective tissue side toward the root surface, although a previous study showed that the orientation of the material did not affect the treatment outcome.[28] The graft was sutured using 5-0 chromic gut, resorbable suture¶ in an interrupted configuration. The flaps were coronally advanced (see recession in Figs. 2A and 2B) to cover the entire graft and were sutured tension free at the CEJ using a 6-0 polypropylene, non-resorbable monofilament suture# in a double-sling configuration,

§ Lugol's solution, Sigma-Aldrich, St. Louis, MO.
‖ Miltex Instruments, Bethpage, NY.
¶ Hu-Friedy, Chicago, IL.
# Prolene, Ethicon, New Brunswick, NJ.

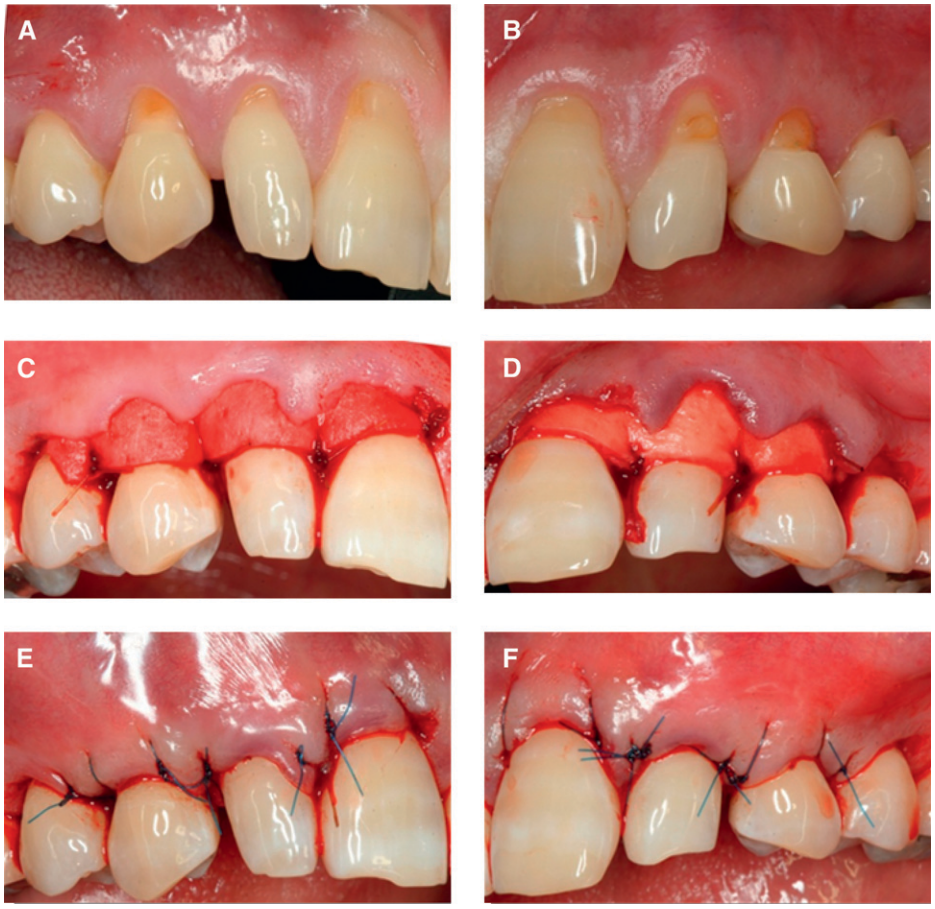

Figure 2.
A) *PDM side at baseline.* ***B)*** *ADM side at baseline.* ***C)*** *PDM grafts sutured at CEJ.* ***D)*** *ADM grafts sutured at CEJ.* ***E)*** *PDM flaps sutured at CEJ.* ***F)*** *ADM flaps sutured at CEJ.*

with interrupted sutures used as needed to secure the papillae (Figs. 2E and 2F).

The same surgical protocol was followed for the control sites. The control ADM was rehydrated in sterile saline as recommended by the manufacturer's guidelines. In every case both contralateral sites were grafted during the same surgical procedure, and the flap design and size were kept consistent between test and control sides.

Post-Surgical Care

The post-surgical care follows previous studies from Cueva et al.[33] and Shin et al.[34] Briefly, gentle ice pack application was used immediately after surgery on a 20-minute intermittent basis for the first 24 hours at both control and test sites. Every patient was given 4 mg of dexamethasone sodium phosphate** either intravenously or intramuscularly. All patients were advised to use cotton-tipped applicators saturated with chlorhexidine gluconate†† 0.12% on the surgical sites for 4 weeks and avoid trauma to the surgical sites. A liquid diet was recommended for the first 48 hours followed by a soft diet for the next 2 weeks. Chlorhexidine gluconate 0.12% rinse was supplied to the patient and used for 4 weeks. Professional plaque control was performed weekly during the first month and at the 3- and 6-month recall. Amoxicillin, 500 mg, three times a day for 7 days was prescribed, and analgesics were prescribed as needed. The sutures were removed at 14 days. The patients were instructed to resume gentle mechanical toothbrushing on the treated sites, as previously described, after 4 weeks of healing. The evaluations of the clinical parameters were performed at baseline and 3- and 6-month appointments (Fig. 3).

Statistical Analysis

The unit of analysis for this study was the patient, with teeth nested within patients. The mean ± SD was calculated for all clinical measurements to 0.5 mm (Table 1). Linear mixed models were constructed to compare ADM to PDM on changes over time in vertical recession, KT, and PD. The fixed-effects portion of each model was procedure (ADM versus PDM), and the random effects portion of each model was the patient, with tooth nested within each patient. Time was specified as the repeated effect, with three levels (baseline, 3 months, and 6 months), with a first-order autoregressive covariance structure. A paired-samples *t* test was computed to compare the two surgical sites on postoperative visual analog scale pain scores.

RESULTS

The 14 subjects consisted of 10 females and four males with an age range of 25 to 59 years (mean, 42.6). Of the 14 patients recruited for this study, five had one bilateral lesion, four had two, and four had three. Each of the 14 subjects had single or multiple bilateral recession defects and three subjects had bilateral recession defects in the maxillary and mandibular arch, which had two separate surgical

** Merck, Whitehouse Station, NJ.
†† Omni Preventive Care, 3M ESPE, Minneapolis, MN.

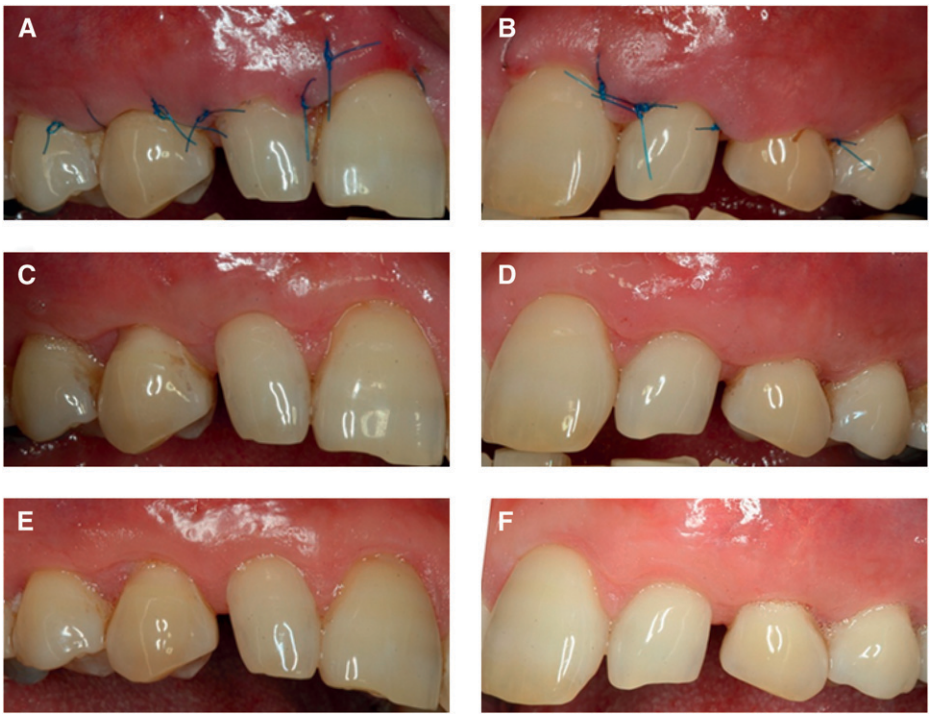

Figure 3.
A) *PDM at 1 week.* ***B)*** *ADM at 1 week.* ***C)*** *PDM at 1 month.* ***D)*** *ADM at 1 month.* ***E)*** *PDM at 6 months.* ***F)*** *ADM at 6 months.*

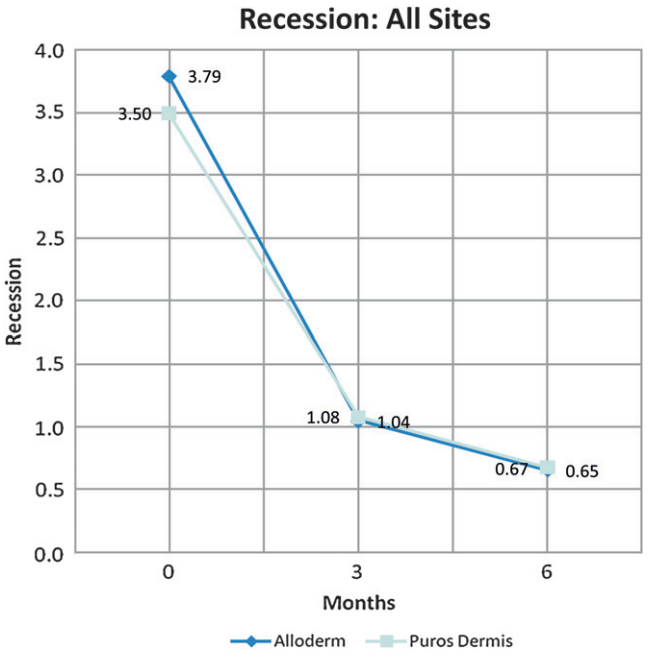

Figure 4.
Comparison of vertical recession between test and control sites over baseline, 3, and 6 months.

procedures accomplished in each arch. There were 26 control and 26 test teeth, each group having 22 Miller Class I defects and four Miller Class III defects. These teeth consisted of seven maxillary anteriors, seven maxillary premolars, five mandibular anteriors, and seven mandibular premolars in each group. All teeth selected tested vital to thermal evaluation.

The linear mixed model for vertical recession indicated that there was no significant effect for treatment (f[1,10.7] = 0.22; $P = 0.65$). All patients significantly improved over time (f[2,16.8] = 110.7; $P < 0.001$). Therefore, all patients showed improved root coverage (vertical recession) (Fig. 4) regardless of the treatment received (Table 1). Patients significantly improved from baseline to 6 months, (t[20] = 13.5; $P < 0.001$) but not from 3 months to 6 months (t[15.6] = 1.9; $P = 0.08$). Moreover, the random effects variance estimate (the effect for patient) was not significant (Wald z = 1.05; $P = 0.29$), indicating that the variability in vertical recession not accounted for by time and treatment was small.

The linear mixed model for KT indicated that there was no significant effect for treatment (f[1,29.7] = 0.40; $P = 0.24$) (Table 1). There was also no significant effect for time (f[2,24.8] = 1.5; $P = 0.25$). Moreover, the random effects variance estimate (the effect for patient) was significant (Wald z = 2.3; $P = 0.02$), suggesting that most of the variability not accounted for by the time and treatment effects was caused by patient-to-patient variation in KT.

The linear mixed model for PD indicated that there was no significant effect for treatment (f[1,29.2] = 1.6; $P = 0.22$). All patients significantly improved over time (f[2,91.1] = 5.7; $P < 0.001$). Therefore, all patients showed improved PDs regardless of the treatment received (Table 1). Patients significantly improved from baseline to 6 months (t[123] = 3.2; $P < 0.01$), but not from 3 months to 6 months (t[85.5] = 0.78; $P = 0.44$). Moreover, the random effects variance estimate (the effect for patient) was not significant (Wald z = 0.84; $P = 0.40$), indicating that the variability in PDs not accounted for by time and treatment was small.

At 6 months, the mean percentage of root coverage for all PDM sites was 81.4% and 83.4% for ADM; the mean percentage of root coverage for all PDM sites with Miller Class I defects was 85% and 87.3% for

Table 1.

Comparison of Clinical Parameters Between Test and Control Sites at Baseline, 3 Months, and 6 Months

Parameter	Baseline SD		3-Month SD		6-Month SD	
	Alloderm	Puros	Alloderm	Puros	Alloderm	Puros
Vertical recession (mm)	3.79 ± 1.47	3.50 ± 1.15	1.04 ± 0.85	1.08 ± 0.91	0.65 ± 0.76	0.67 ± 0.76
Keratinized tissue (mm)	2.83 ± 1.17	2.60 ± 1.13	3.00 ± 0.94	2.71 ± 0.94	2.94 ± 0.85	2.85 ± 0.83
Probing depth (mm)	1.15 ± 0.37	1.23 ± 0.43	1.04 ± 0.20	1.08 ± 0.27	0.96 ± 0.20	1.08 ± 0.27

ADM; the mean percentage of root coverage for all PDM sites with Miller Class III defects was 61.3% and 62.5% for ADM. None of these parameters were significantly different between ADM and PDM.

There was not a significant difference between the two surgical sites on postoperative pain ($t[16] = 0.93$; $P = 0.37$). The mean patient pain evaluation was 22.9 ± 8.20 mm (range, 12 to 38) for PDM sites and 23.6 ± 9.40 mm (range, 9 to 42) for ADM sites.

At each time interval, 14 subjects were analyzed. No adverse events occurred during the study and no subjects were excluded from the analysis. All subjects were available for follow-up.

DISCUSSION

Results indicate that the combination of Zucchelli incisions and CAF with both materials results in an effective treatment method. Both groups had similar measurements with very few differences and no statistically significant differences. Clinical evaluations were also similar. Both KT and PD remained stable over the 6-month time period.

In the present study, both test and control grafts yielded significant root coverage from baseline to 6 months. The mean percentage of root coverage for all sites including Miller Class I and III was 81.4% ± 19.9% in the test group and 83.4% ± 19.2% in the control group. The mean root coverage results of this study were lower than other studies,[2,8] which obtained mean root coverage of 97% with either FGGs or CAF; these studies also achieved complete root coverage at 84% to 90% of the Miller Class I and II sites. When the present data were evaluated in terms of Miller Class I defects, the mean root coverage improved to 85% (PDM) and 87.3% (ADM).

Miller[2] has stated that his high success rates and predictability of root coverage were based on strict execution of a well-defined surgical technique and proper classification of the recession defects. Both tenants of Miller's success undoubtedly improve with advanced surgical experience. To test these concepts, the present data were further analyzed to evaluate changes in success rates with increased surgical experience at Miller Class I sites. The 14 subjects were divided sequentially into the first seven subjects treated and the last seven subjects treated. The first seven subjects had 21 sites with a mean root coverage of 79.4% and complete root coverage at 23.6% of the sites. The last seven subjects had 23 sites with a mean root coverage of 92.3% and complete root coverage at 74.3% of the sites. The *t* test showed statistically significant improvement in mean root coverage ($P = 0.01035$) from the first eight subjects treated to the last nine subjects treated. These data support Miller's suggestion that predictable root coverage is a byproduct of surgical technique, which improves with surgical experience.

The results of the present study compare favorably with previous studies reporting a short-term evaluation after ADM grafting, including predictable root coverage, stable PD, and KT.[24-28,35] The results of the present study showed PD to be stable over 6 months (with no bleeding on probing): PD = 1.08 ± 0.27 mm (PDM) and 0.96 ± 0.20 mm (ADM). The results of the present study also show KT to be stable over 6 months: change in KT from baseline to 6 months was 0.12 ± 0.50 mm (PDM) and 0.12 ± 0.76 mm (ADM).

Pini Prato and Tinti[36] investigated flap tension in CAF surgeries and concluded that minimal flap tension does not influence recession reduction, although they continued by stating that the higher the flap tension, the lower the recession reduction, suggesting that there may be a critical flap tension beyond which flap healing and root coverage are reduced. In the present study all flaps were considered to be tension free because of extensive undermining of the apical partial-thickness portion before suturing the flap at the level of the CEJ. Therefore, the present study can draw no conclusion concerning a critical flap tension.

Previous studies have shown that ADM increases marginal tissue thickness histologically[36] and clinically.[25-28] It has been suggested that a thin gingival phenotype and delicate marginal tissues could be

a factor in increasing the risk for gingival recession. These suggestions by Müller and Eger[37,38] led to the idea that an increase in gingival thickness resulting from a soft tissue graft may prevent further recession in patients with a thin periodontal "phenotype." The concept of "thicker attached tissue" preventing future recession and attachment loss at sites with a thin periodontium had no long-term analysis until recently. In 2008, Agudio et al.[39] reported on a retrospective, long-term study of FGG placed 10 to 25 years earlier. The grafts were positioned at the presurgical level of the gingival margin or in a submarginal position. The results show that from baseline to 1 year after surgery, the gingival margin shifted coronally 0.8 mm and KT increased 4.2 mm. From 1 year after surgery to the end of the follow-up period (10 to 25 years), the gingival margin shifted coronally 0.6 mm and the overall KT decreased 0.7 mm. During this time the PD remained stable. In our study, the grafting materials used showed uniform thickness. The PDM material was slightly thicker than the ADM material.

Until the report by Agudio et al.,[39] the long-term success of soft tissue grafting beyond 2 years was empirical. Agudio et al.[39] has shown the autogenous soft tissue graft to be stable over 25 years. Several reports[29,40] have compared the human histology of CTG to ADM for root coverage procedures. These reports yielded similar results stating that both CTG and ADM formed a band of dense collagenous tissue when placed beneath CAF. The gingival attachment resulted from a combination of long junctional epithelium and connective tissue adhesion and was comparable for both groups. At 6 months postoperatively, the overall histologic outcomes were similar for both CT and ADM grafts. Thus, it could be assumed that with similar histology to an autogenous, free soft-tissue graft, the acellular dermal matrix allograft would also be resistant to future recession long term. It has been reported that the histology of PDM[30,41] has a similar structure of collagen matrix and vascular channels, and is reported to undergo a similar wound healing with respect to vascular endothelial budding and fibroblast invasion as ADM. It is therefore reasonable to assume that PDM would have similar long-term results.

It has been reported recently that tobacco smoking could have a negative influence on gingival recession reduction from root coverage procedures.[42] Because none of the participants in our study smoked, we can add no evidence to this topic.

Our study presented two main limitations: one was the 6-month short-term evaluation, and the second was the lack of histologic evaluation. Both limitations are essential elements to understand the effectiveness of these two materials, and further study is recommended to evaluate these issues.

CONCLUSIONS

Within the limitations of this study, the results show significant root coverage from baseline to 6 months with stable PD in both acellular dermal matrix allograft products. No significant differences between the two with respect to percentage of root coverage, KT, or PD were found.

ACKNOWLEDGMENTS

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