Gingival Phenotype Modification as a Result of Root Coverage Procedure with Two Human Dermal Matrices: Long-Term Assessment of a Randomized Clinical Trial



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The gingival thickness (GT) and keratinized tissue width (KTW) constitute the gingival phenotype, a concept that has received a great deal of appreciation in recent years. Gingival phenotype modification has been achieved via different surgical techniques and grafting materials. Despite the superiority of autogenous grafts, their increased patient morbidity and limited recourse has led to the development of graft substitutes. The human dermal matrix is a notable example that, depending on its processing method, can become freeze-dried or solvent-dehydrated acellular dermal matrix (FDADM and SDADM, respectively). This article reports the 9-year outcomes of a randomized clinical trial regarding gingival phenotype modification following root coverage with FDADM and SDADM. Twelve of the original 20 patients were available at the 9-year follow-up. Overall, the outcomes of gingival phenotype modification were maintained in both groups and at all sites after 9 years. For KTW, an incremental increase was observed over time in both groups, and minimal or no changes were noted in GT from the 1-year recall to the 9-year recall. However, the gingival margin level showed an apical shift for both groups. Int J Periodontics Restorative Dent 2021;41:719–726. doi: 10.11607/prd.5283

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The new classification of periodontal and peri-implant diseases and conditions highlights the importance of the gingival phenotype.[1] As stated, the gingival phenotype, which is comprised of the gingival thickness (GT) and keratinized tissue width (KTW), plays a role on the development of gingival recessions (GRs), where thin phenotypes are more prone to this condition.[1] Several techniques have been identified to modify the gingival phenotype, with autogenous grafts showing superior outcomes for both GT and KTW.[2–4] Nevertheless, in order to reduce patient morbidity, risk of complications, and surgical time,[5,6] several soft tissue graft alternatives have been explored, such as the collagen matrix, acellular dermal matrix (ADM), and living cellular constructs.[7–9] ADM is obtained from human skin that has undergone a decellularization process, resulting in an extracellular matrix scaffold devoid of epithelium and cellular components.[7] It has been suggested that the processing methods for obtaining ADM may affect its clinical outcomes.[10] However, limited evidence is available in the literature, most of which is short-term data.

The long-term outcomes obtained after periodontal plastic surgery have become a topic of interest recently,[11–16] especially for non-autogenous scaffold materials.[14,15]

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Few studies have addressed the long-term outcomes of gingival phenotype modification therapy (PMT) with ADM following root coverage procedures. Therefore, the present study evaluated the long-term status of the gingival phenotype at sites that previously underwent a root coverage procedure with two differently processed ADMs.

Material and Methods

Study Design and Original Intervention

The present article reports on a long-term follow-up of a previous randomized clinical trial (RCT) conducted from November 2009 to December 2010[17] (clinicaltrials.gov identifier: NCT00881959). The CONSORT statement for improving the quality of reports of parallel RCTs was followed in the preparation of this manuscript. Informed consent was obtained from all subjects who participated in this follow-up study.

Briefly, the original RCT[17] recruited subjects who presented with a recession type 1 defect ≥ 2 mm on the facial aspect of at least one maxillary nonmolar tooth.[1] All individuals were healthy adults who were able to understand and comply with all of the instructions and were able to maintain good oral hygiene as educated. Patients received full-mouth supragingival scaling, polishing, and oral hygiene instructions 2 months before the surgery. Additionally, patients were instructed on an optimal toothbrushing technique, which was re-emphasized at every appointment. Patients were randomly allocated to receive treatment for a single GR defect via the coronally advanced flap method, using either a freeze-dried acellular dermal matrix (FDADM; AlloDerm, BioHorizons) or a solvent-dehydrated acellular dermal matrix (SDADM; Puros Dermis, Zimmer Biomet). Patients were not made aware of the treatment they were selected to receive. Randomization was performed prior to the surgery, as the rehydration process for both ADMs had to be initiated before the surgical procedure, according to the manufacturers' instruction (Fig 1). FDADM was hydrated in two separate saline baths, 10 minutes each, for a total of 20 minutes. SDADM was hydrated for 5 to 30 minutes in an endotoxin-free 0.9% sterile saline at room temperature.

All surgical procedures were conducted at the University of Michigan School of Dentistry following a strict protocol and calibration sessions.[18] Two diverging vertical releasing incisions were performed at the mesial and distal line angles of the tooth to be treated, starting at a distance equal to the recession depth plus 1 mm from the adjacent papilla tip. A full-thickness mucoperiosteal flap was then elevated beyond the mucogingival junction. Adjacent gingival papillae were deepithelialized using a scalpel blade. The exposed root surfaces were planed with rotary instruments and conditioned with ethylenediaminetetraacetic acid.[19] Periosteal scoring was performed to obtain a tension-free flap. The rehydrated ADM (FDAMD or SDADM) was then trimmed to cover the exposed root 3 mm beyond the lateral and apical root surfaces. The ADM graft was sutured at the level of the cementoenamel junction (CEJ) using a single 5-0 fast-absorbing polyglycolic acid sling suture. The overlying flap was then advanced to a level 1 to 2 mm coronal to the CEJ using the sling and tag suture technique, as previously described.[18,20] Postoperative instructions were provided for all subjects both verbally and in the written form. Postoperative medications included 600 mg ibuprofen over 6 to 8 hours, as needed, and 500 mg amoxicillin three times daily for 10 days, starting 1 hour before surgery.

After suture removal at 2 weeks, patients were instructed to resume an atraumatic brushing technique using a soft-bristle toothbrush. A session of clinical assessment and professional cleaning with oral hygiene instructions was performed at 1, 3, 6, and 12 months postoperative and twice a year thereafter.

Clinical Measurements at the 9-Year Recall

At the 9-year recall, the following clinical measures were obtained by a single blinded and calibrated examiner (R.D.G.), as described in the original protocol, using a periodontal probe (PCP UNC 15, Hu-Friedy) with the original customized acrylic resin stents that were fabricated for the original trial: recession depth (RECd), probing depth (PD), KTW, and GT. Measurements were rounded to

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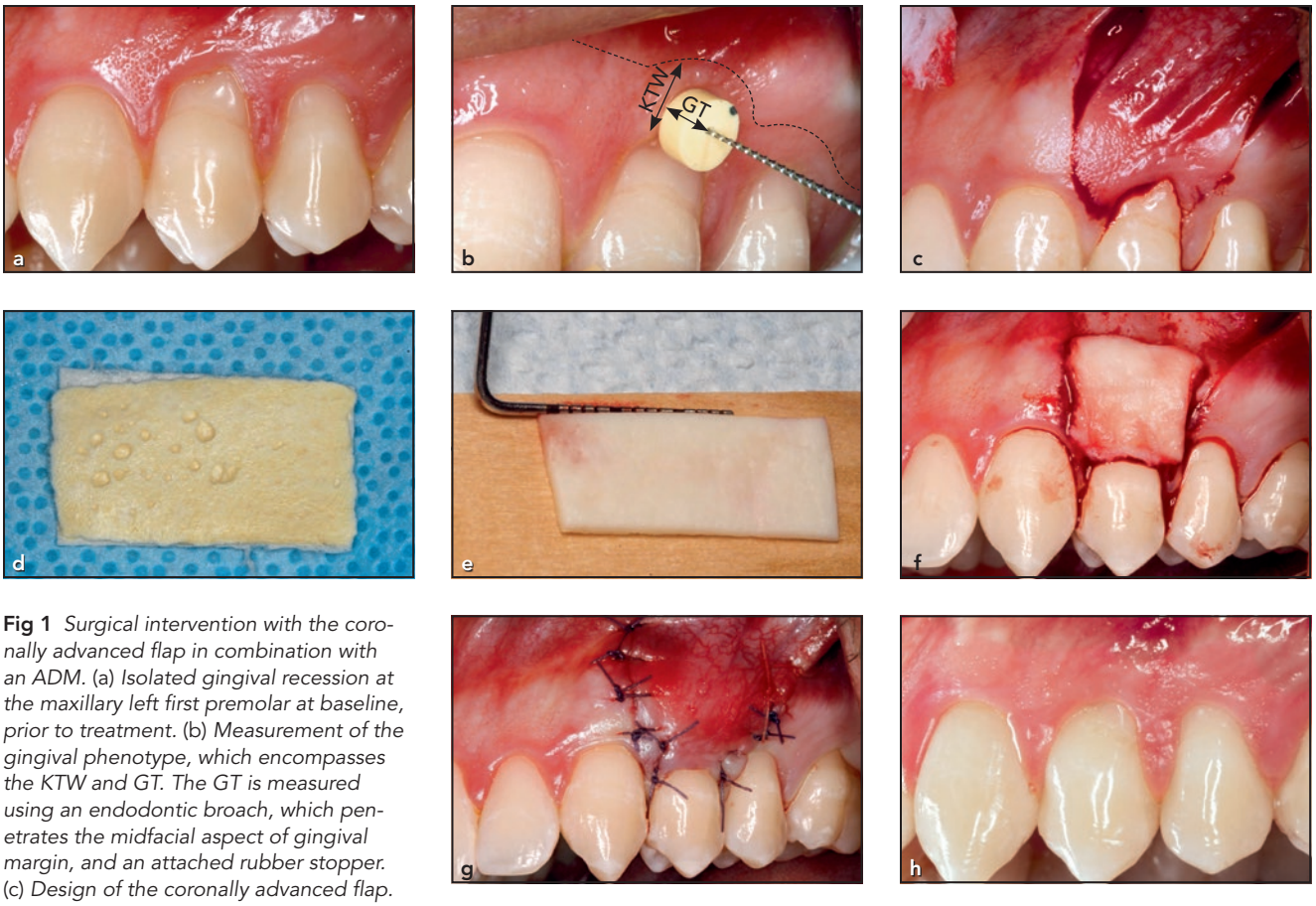


Fig 1 *Surgical intervention with the coronally advanced flap in combination with an ADM.* (a) *Isolated gingival recession at the maxillary left first premolar at baseline, prior to treatment.* (b) *Measurement of the gingival phenotype, which encompasses the KTW and GT. The GT is measured using an endodontic broach, which penetrates the midfacial aspect of gingival margin, and an attached rubber stopper.* (c) *Design of the coronally advanced flap. Based on the randomization results, either* (d) *an FDADM or* (e) *an SDADM was used as a graft material.* (f) *Here, an SDADM was used and stabilized over the root surface at the level of the CEJ by a single 5-0 fast-absorbing polyglycolic acid sling suture.* (g) *Flap advancement was utilized to cover the CEJ by 1 to 2 mm and to close the surgical site.* (h) *Clinical results at the 9-year recall.*

the nearest 0.5 mm. Additionally, a color-coded probe (Colorvue Biotype probe, Hu-Friedy)[21] was used to compare the gingival phenotype at each treated site to their contralateral teeth (only if the contralateral teeth had not received a mucogingival procedure). The gingival phenotype assessed with this method was classified either as thin Ph-c (where "Ph" stands for gingival phenotype and "c" stands for color-coded probe), medium Ph-c, thick Ph-c, or very thick Ph-c.[22,23] In addition, the esthetic outcomes were evaluated using the root coverage esthetic score (RES)[24] to compare the changes from the 1-year recall to the 9-year recall.

Study Outcomes

The main outcome of this study was to assess the changes in the gingival phenotype from 1 to 9 years through evaluation of GT and KTW. The secondary outcome of the present study was to observe the behavior of the gingival margin (in terms of mean RECd and mean root coverage [mRC]) and evaluate the changes in RES scores for both groups (FDADM and SDADM) from 1 year to 9 years. The final study outcome was to assess the Ph-c of the FDAMD and SDADM sites relative to their increased GT (assessed by changes from pretreatment baseline to the 9-year recall).

Data Analysis

The intermediate time point data from the original trial was retrieved

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for the available patients at the 9-year recall. Descriptive analysis was used for presentation of the gathered clinical data with means (in millimeters) and SDs for continuous variables of RECd, PD, KTW, GT, and RES. Complete root coverage (CRC) was expressed as a percentage for sites that achieved a complete recession coverage at 1 year and those that maintained their complete coverage at 9 years. Ph-c was reported descriptively, as the percentage of sites with a relative thin, medium, thick, or very thick Ph-c among each group. Due to the number of participants who were unavailable at the long-term recall, no statistical testing was performed to compare FDADM and SDADM treatment groups, and data presentation was carried out through descriptive statistics.

Results

Twelve patients (7 women, 5 men) were available at the 9-year recall, corresponding to a 60% response rate (Fig 2). Seven were treated with FDADM (mean age: 46.4 ± 16 years), and 5 received SDADM (mean age: 37.2 ± 14.8 years). The clinical parameters for both groups at baseline and the subsequent time points are presented in Table 1. Figure 3 shows a root coverage procedure for both FDADM and SDADM groups and their outcomes over time.

With regard to the parameters of gingival phenotype, an increase in KTW was observed from the 1-year to the 9-year recall at all sites (means of 0.64 ± 0.24 mm and 0.8 ± 0.57 mm in the FDADM and SDADM groups, respectively). Whereas with GT, a significant increase was observed from baseline (pretreatment) to the early follow-up appointments (3, 6, and 12 months), which was maintained in both groups over time, as they had minimal or no changes at the 9-year recall (Table 1).

When the color-coded probe was used at the 9-year recall, 85% of FDADM cases (six of seven) and 80% of SDADM cases (four of five) displayed a thicker Ph-c than their contralateral sites. Among the FDADM-treated sites, two showed a thick Ph-c and five showed a medium Ph-c; at their contralateral sites, six showed a thin Ph-c, and one showed a medium Ph-c. For the SDADM group, three of the treated sites showed a medium Ph-c and two showed a thick Ph-c; at their contralateral sites, two presented with a medium Ph-c and three showed a thin Ph-c.

Both ADM groups showed a similar tendency toward an apical shift of the gingival margin, with an average increased RECd of 0.42 ± 0.6 mm in the FDADM group and 0.3 ± 0.44 mm in the SDADM group (17.14% and 11.16% mRC reductions, respectively). There was also a reduction of a single CRC case—from 3 months at the 1-year time point, and from 1 year at the 9-year follow-up—in the FDADM group, whereas the original two CRC cases in the SDADM group were maintained from 1 to 9 years.

PD measures for both groups seemed relatively unchanged from 1 to 9 years (0 ± 0.64 mm in the FDADM group and 0.3 ± 0.83 mm in the SDADM group).

Regarding the RES scores at 1 year, the FDADM and SDADM groups showed averages of 7.1 ± 1.5 and 7.4 ± 1.3, respectively. However, the RES assessment at 9 years showed a slight decrease in both groups (6.2 ± 1.8 for FDADM and 6.3 ± 1.2 for SDADM). Lastly, one patient in the FDADM group reported minor discomfort when brushing the previously treated areas.

Discussion

There is no doubt that the outcomes of gingival PMT largely depend on the properties of the utilized graft material.[2,4,7] The 1-year results of the SDADM group in the present report showed a mean KTW increase of approximately 0.5 mm, while minimal changes were observed among the FDADM-treated sites. The mean KTW increase in the SDADM group may be due to the notion that this processing method fully preserves the structure of the extracellular matrix, which promotes the migration of keratinocytes from the surrounding host tissues.[7] Therefore, it is possible that the processing methods to obtain ADM may affect scaffold characteristics, such as cell penetration and proliferation.[10] Additionally, gains in KTW were observed at the 9-year follow-up at all treated sites, irrespective of the ADM group, which is likely due to the concept that the mucogingival line tends to regain its genetically determined position[25] rather than

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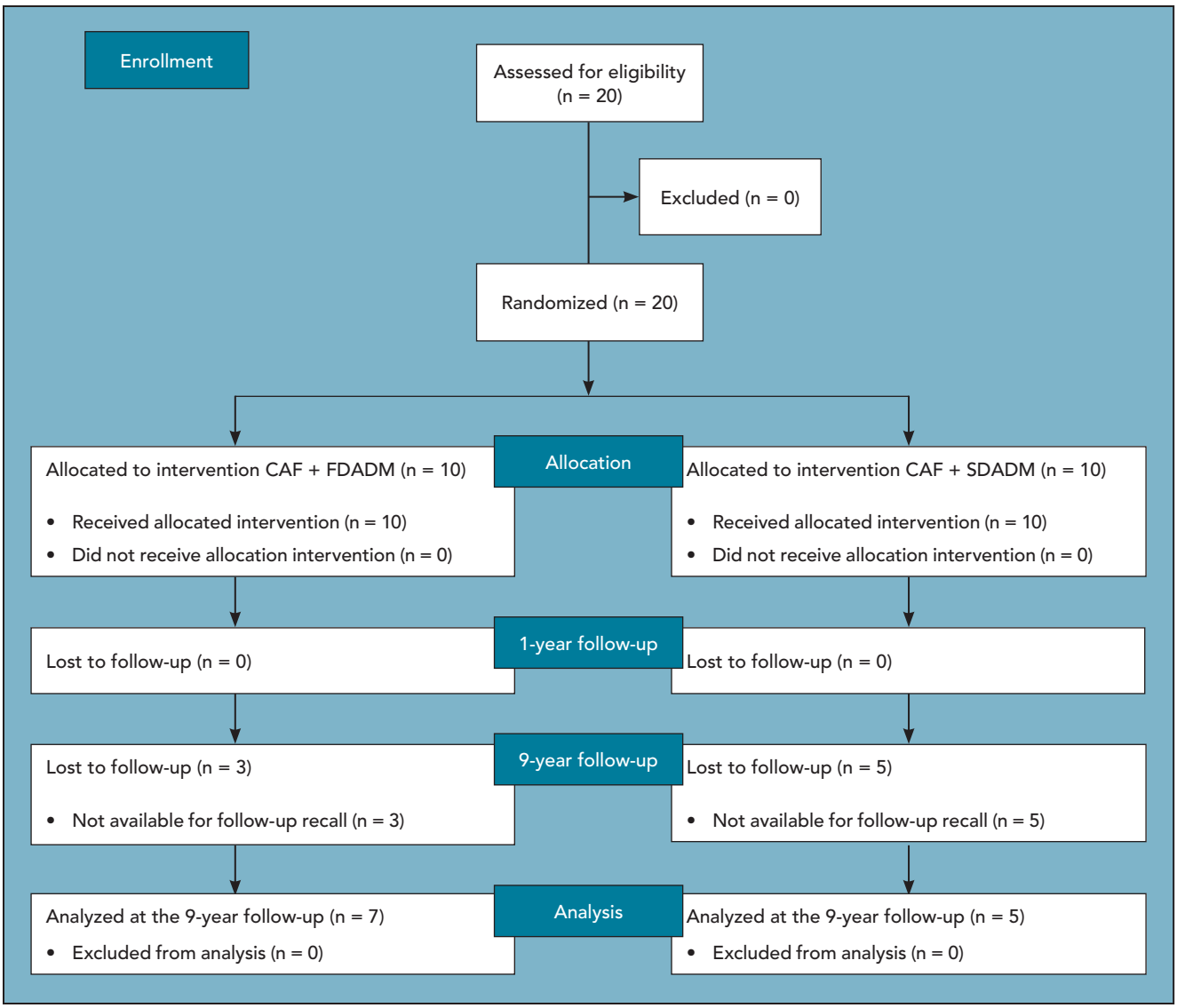


Fig 2 *Flowchart of the study procedure. CAF = coronally advanced flap; FDADM = freeze-dried acellular dermal matrix; SDADM = solvent-dehydrated acellular dermal matrix.*

the ability of ADM alone to significantly increase the zone of KTW.[2,14]

Furthermore, both ADM materials obtained a substantial GT gain during the early follow-up time points (3, 6, and 12 months). Interestingly, the increased GT seems to be maintained overtime with minimal or no changes after 9 years. When the color-coded probe was used to evaluate the relative Ph-c of the treated sites, most of the ADM-treated sites had a thicker Ph-c compared to their contralateral sites. While this needs caution in interpretation due to the unavailability of color-coded probes at baseline and therefore a lack of a direct comparison, it could be speculated that this result may further corroborate the sustained GT at the ADM-treated sites.[2,7,15]

Among the advantages of PMT, it has been advocated that a gingival phenotype with adequate GT and KTW is less prone to developing GRs[1,15] and noncarious cervical

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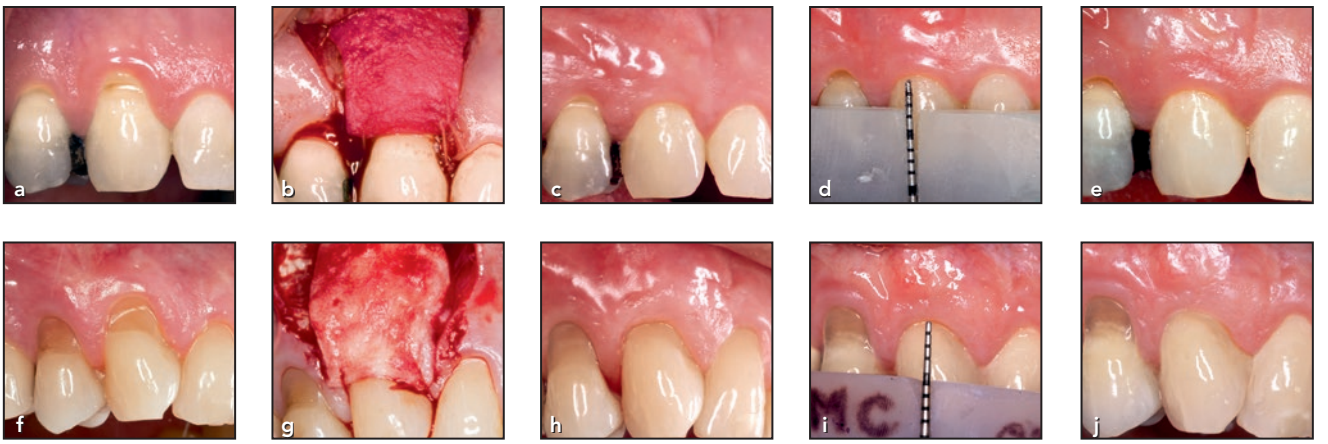


Fig 3 *Long-term treatment outcomes using* (a to e) *FDADM and* (f to j) *SDADM.* (a and f) *Pretreatment baseline of the teeth to be treated.* (b and g) *Graft stabilization.* (c and h) *Clinical results 1 year after the surgical procedure.* (d and i) *At the 9-year recall, the original customized acrylic stents were used to guide the calibrated examiner when performing consistent measurements.* (e and j) *Clinical outcomes at 9 years.*

Table 1 Gingival Phenotype and Gingival Margin Parameters at Baseline, 3 Months, 6 Months, 1 Year, and 9 Years for Both Groups

		Time point					Differences	
Clinical parameter	ADM group	Baseline	3 mo	6 mo	1 y	9 y	1 y to 9 y	Baseline to 9 y
Gingival phenotype								
GT, mm	FDADM	1.42 ± 0.53	1.85 ± 0.62	1.64 ± 0.62	1.78 ± 0.48	1.98 ± 0.53	0.14 ± 0.69	0.57 ± 0.6
	SDADM	1.2 ± 0.27	1.8 ± 0.44	1.8 ± 0.27	1.8 ± 0.27	1.8 ± 0.27	0 ± 0	0.6 ± 0.54
KTW, mm	FDADM	2.35 ± 0.55	2.42 ± 0.61	2.35 ± 0.74	2.42 ± 0.61	3.07 ± 0.78	0.64 ± 0.24	0.71 ± 0.9
	SDADM	1.9 ± 0.74	1.9 ± 0.89	2.1 ± 0.89	2.4 ± 0.65	3.2 ± 0.44	0.8 ± 0.57	1.3 ± 0.83
Gingival margin								
RECd, mm	FDADM	2.5 ± 0.5	0.42 ± 0.61	0.64 ± 0.74	0.57 ± 0.6	1 ± 0.86	0.42 ± 0.6	–1.5 ± 1
	SDADM	2.6 ± 0.54	0.7 ± 0.97	0.8 ± 1.09	0.6 ± 0.65	0.9 ± 0.89	0.3 ± 0.44	–1.7 ± 0.83
mRC, %	FDADM	–	83.1 ± 23.57	74.28 ± 30.71	75.95 ± 25.12	58.8 ± 38.2	–17.14 ± 23.6	–
	SDADM	–	76.6 ± 32.48	73.3 ± 36.51	78.3 ± 21.73	66.6 ± 31.2	–11.6 ± 16.2	–
CRC, n (%)	FDADM	–	4 (57.1)	3 (42.8)	3 (42.8)	2 (28.5)	–1 (–14.3)	–
	SDADM	–	3 (60)	3 (60)	2 (40)	2 (40)	0 (0)	–

ADM = acellular dermal matrix; GT = gingival thickness; KTW = keratinized tissue width; RECd = recession depth; mRC = mean root coverage; CRC = complete root coverage; FDADM = freeze-dried ADM; SDADM = solvent-dehydrated ADM.
All values except CRC are expressed as mean ± SD.
[a]Changes in the clinical parameters from baseline or 1 year to 9 years reflect the subtraction of values at the final 9-year recall from the baseline or 1-year time points.

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lesions,[26] facilitating the maintenance of oral hygiene at the same time.[2,27,28]

In line with the literature,[14–16] a trend for relapse in the gingival margin was observed after 9 years for both FDADM, and SDADM groups, which was also reflected in the RES values that dropped from 7.1 and 7.4 at 1 year, respectively, to 6.2 and 6.3 at the 9-year recall, respectively.[29]

Finally, the present study results should be interpreted with caution. The relatively high number of unavailable patients at the 9-year recall hindered further statistical analysis among the two ADM groups. Nonetheless, many of the stated limitations tend to be familiar drawbacks of long-term follow-up studies, especially in an academic institute such as a dental school.

Conclusions

Within its limitations, it was observed that root coverage procedures with FDADM and SDADM resulted in a modification of the gingival phenotype that was maintained over time. In addition, an increased KTW was observed at the 9-year recall in both FDADM and SDADM groups.

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