



Acellular dermal matrix allograft versus autogenous connective tissue grafts for thickening soft tissue and covering multiple gingival recessions: a 5-year preference clinical study

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Objectives: The present preference clinical trial compared the long-term outcome of acellular dermal matrix allograft (ADMA) versus autogenous connective tissue graft (CTG) in the treatment of gingival recessions. **Method and materials:** Thirty-nine consecutive patients with 233 Miller Class I and II recessions were treated by one operator (MS) with coronally advanced flaps and in addition either ADMA or CTG harvested from their palate. Clinical parameters were measured by an independent and masked assessor at baseline, 6 months, and 5 years. **Results:** Thirty-two patients could be recruited for long-term examination (seven dropouts). At 6 months and 5 years, all clinical parameters showed significant improvements in both groups with slightly better but statistically not significant clinical results for CTGs. At 5 years, the CTG group

revealed an additional gain of keratinized mucosa width (t6m-0: CTG 1.88 mm, ADMA 1.04 mm, $P = .081$; and t5y-0: CTG 3.98 mm, ADMA 3.06 mm, $P = .01$) compared to 6 months, whereas the mean for ADMAs remained stable (intergroup comparison statistically significant, $P = .010$). In all other parameters in both groups, slight but not statistically significant relapses were detected. Only one minor postoperative complication at one ADMA-treated site occurred. **Conclusions:** Regarding the long-term results, ADMA could be an alternative treatment option to thicken soft tissue and to cover multiple gingival recessions. If the gain of keratinized mucosa width is considered as a main goal, CTG may have a slight advantage over ADMA. (*Quintessence Int* 2019;50:278-285; doi: 10.3290/j.qi.a42160)

Key words: acellular dermal matrix, connective tissue, gingival recession, long-term outcome, root coverage

Gingival recession (GR) is defined as the oral exposure of the root surface because of an apical displacement of the soft tissue with respect to the cemento-enamel junction (CEJ).¹ Indications for the surgical coverage of exposed roots are patients' esthetic demands, as well as increased dentin hypersensitivity and root caries susceptibility, or if it hampers proper plaque removal.² Chronic traumatic brushing and iatrogenic factors such as orthodontic treatment or violation of the soft tissue by restorative treatment, and anatomical factors like a thin biotype or dehiscence of the buccal bone are the main conditions leading to the development of these defects.^{3,4} Several mucogingival procedures have been proposed and proven predictable for the correction of dental root exposition, such as laterally positioned flaps,^{5,6} coronally advanced flaps,⁷ subepithelial connective tis-

sue grafts (CTGs),⁸⁻¹⁰ acellular dermal matrix allograft (ADMA),^{11,12} and guided tissue regeneration.^{13,14} CTG combined with different flap designs has been considered the "gold standard" technique.¹⁵ However, harvesting the palatal area is time-consuming and increases patient's postoperative morbidity, such as bleeding, pain, and hyposensitivity.^{8,16,17} Patients with multiple recessions may need more and staged surgeries in case of a lack of sufficient donor material. Looking for an option to avoid those disadvantages, ADMA was developed to substitute for the autogenous CTG. In terms of recession reduction, the short-term results showed similar outcomes between CTG and ADMA.^{11,12,18-21} The primary aim of this preference controlled clinical trial was to compare the long-term stability of these two techniques 5 years after surgery.

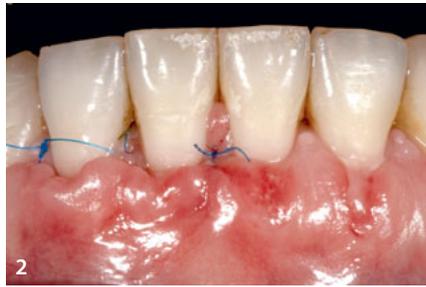
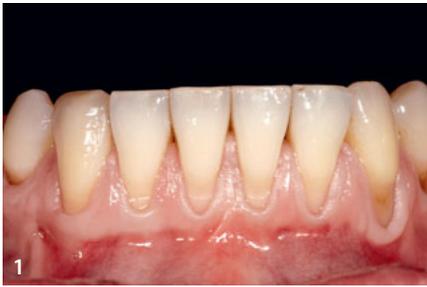


Fig 1 Connective tissue graft, baseline, in a multi-recession case.
Fig 2 Connective tissue graft, 3 days postoperatively.
Fig 3 Connective tissue graft, 6-month result.
Fig 4 Connective tissue graft, 8-year result.

Method and materials

Study design and participants

The present preference controlled clinical trial was conducted according to the Declaration of Helsinki on clinical research involving humans. The study protocol was approved by the Ethics Commission International Freiburg, Germany (study code: TM-MS-2006-01; feci Code 010/1462). The study population was composed of patients (≥ 18 years) who requested coverage of more than one tooth affected by Miller Class I or II recessions (no visible bone loss of the interdental papilla and distance between the CEJ and bone crest ≤ 2.5 mm measured on periapical radiographs; however, when present, Miller Class III and IV recessions were also treated but not considered in the analyses). Patients affected by periodontitis, any pathologic systemic conditions, poor oral hygiene and motivation (plaque and bleeding scores $> 15\%$ before surgery), and a current smoking habit (exsmokers could be included if not smoking for at least 6 months) were excluded, as well as pregnant women and participants in other clinical studies within the last 6 months before surgery. The same clinician (MS) recruited and treated all patients in his private practice. Presurgical therapy

included detailed instruction in oral hygiene and professional tooth cleaning when required.

Patients who asked for a root coverage procedure due to esthetic reasons and meeting the inclusion criteria were asked to join the study. The surgeon explained any potential advantages and disadvantages of using autogenous CTG or ADMA for recession coverage. The first 21 patients who preferred the ADMA to thicken their tissue and the first 21 who favored CTG from their own palate were considered eligible and treated. There was no external influence on the decision of the patient. None of the patients was informed about the status of recruitment to avoid the bias that patients who preferred one method were forced to choose the other method to be a part of the study. The surgeries took place between September 2005 and January 2010. After excluding all teeth with Miller Class III and IV, due to their unpredictable outcome and thus a higher risk of bias, 39 patients (CTG, $n = 19$; and ADMA, $n = 20$) and 233 recessions remained for the statistical analysis of the 6-month follow-up examination. Out of those patients the authors could recruit 15 in the CTG group (one not willing to attend the follow-up, three moved and could not be reached) and 17 in the ADMA group (one not willing to attend follow-up, two moved and could not be reached) for the 5-year investigation.



Fig 5 Dermis, baseline, in a multi-recession case.
Fig 6 Dermis, matrix in place.
Fig 7 Dermis, 6-month result.
Fig 8 Dermis, 5-year result.

Surgical procedures

After local anesthesia, ultrasonic devices, rotating burs, and curettes were used to scale and plane the exposed roots to the bottom of the pocket, preventing damage to the periodontal ligament by avoiding deeper instrumentation. Prominent roots were flattened if necessary, but no chemical conditioning was implemented. According to the incision outline described by Zucchelli and De Sanctis,²² the operator performed a coronally displaced split-thickness flap. Mobilization of the flap was considered to be adequate as soon as it passively stayed at a level slightly coronal to the CEJ after coronal advancement. Depending on the patient's choice, subepithelial CTG harvested from the palate or ADMA were used to increase the thickness of the gingival tissue (Figs 1 to 8).

CTGs were harvested from the palate in the area between the canine and first molar. A horizontal incision 3 mm below the sulcus and 8 to 10 mm deep was applied without any releasing incision. The incision was as close as possible to the surface to ensure sufficient tissue thickness to avoid tissue necrosis. The second incision was parallel at a distance of 1 mm closer to the sulcus. The tissue in between was separated with two internal vertical incisions and a deep horizontal incision and removed. In contrast to the single incision technique described by Hürzeler and Weng,²³ the periosteum was left in place by this technique. The wound was closed by a running

suture and the epithelium was removed from the CTG. The graft was trimmed and adapted to the exposed roots 1 mm below the CEJ and fixed to the recipient teeth with sling sutures (Prolene, 6-0, Braun). After deepithelization of the papilla, the flap was coronally advanced and fixed with separate sling sutures 1 mm above the CEJ. The knots were placed on the palatal side to minimize patient discomfort.

When the patient preferred the ADMA, Tutoplast Dermis Allograft Tissue Matrix (Tutogen Medical; now available as Puros Dermis, Zimmer Dental) was used as a human dermis graft. According to the claims of the manufacturer, the Tutoplast process inactivates contamination by bacteria, virus, and prion and eliminates antigenicity without changes in the natural collagen matrix or mechanical properties of the graft.^{24,25} The manufacturer claimed these properties also for allogeneic bone processed with similar proceedings. Various publications proved that fat and proteins remained at very low levels in bone grafts processed with the same technique.²⁶⁻²⁸ It was discussed that these remnants could cause antigenic reactions. Material proving this for collagen matrices are lacking. This solvent-dried material is packaged with the absence of residual antibiotics and terminally sterilized by low-dose gamma irradiation. After 30 minutes of rehydration in sterile saline, the ADMA was adapted in size, localized underneath the flap, and fixed at the recipient site simultaneous to the procedure at the CTG sites.

Postsurgical protocol

All patients were placed on chlorhexidine rinse (0.12%) twice a day for 1 minute for 2 weeks, and nonsteroidal anti-inflammatory and analgesic medication (ibuprofen 400 mg) was prescribed. Patients were asked to avoid any mechanical trauma to the surgical site until sutures were removed after 14 days. The patients were enrolled in a recall 1, 2 and 6 months after surgery, which included professional plaque control, remotivation and reinstruction of a gentle roll technique with a soft toothbrush.

Clinical measurements

The clinical examination was performed prior to surgery (T0), 6 months after (T6m), and 5 years (T5y) after with a periodontal probe (PCP-UNC 15 probe, Hu-Friedy) using a force of 0.2 Ncm to the nearest 0.5 mm. Outcome measures were:

- Gingival recession (GR) changes: distance in mm between the most apical position of the gingiva on the buccal side and the CEJ (if not visible, the assessor estimated the CEJ position as well as possible. Reference was crown width-length ratio, neighboring teeth, and corresponding teeth).
- Gingival biotype (BIO) changes: if the probe shone through the tissue, the biotype was classified as thin. If it was not visible, it was considered as thick.
- Keratinized mucosa width (KM) changes: measured from gingival margin to the mucogingival junction.
- Probing pocket depth (PPD) changes: measured from the most apical position of the gingiva on the buccal side of the tooth to the bottom of the gingival sulcus.
- Clinical attachment level (CAL) changes: calculated by the formula: $CAL = GR + PPD$.
- Complications: any complication that occurred during or after the surgery for the entire follow-up period.

Statistical analysis

A biostatistician with experience in dentistry analyzed the data. A sample size calculation was not performed. This study tested the null hypothesis that there were no differences between CTG and ADMA against the alternative hypothesis of a difference. The statistical unit of the analyses was the patient. Quantitative values as well as the differences between time points were presented as mean and standard deviation (SD), minimum and maximum, as well as quartiles. Values were tested for normal distribution using the Shapiro-Wilk test. In case of significant deviations from normal distribution, nonparametric

Table 1 Baseline patient and site characteristics

Characteristic	CTG (n = 19)	ADMA (n = 20)
Number of females	17	15
Age (range), y	43.6 (24–64)	46.6 (25–69)
Mean number of recessions per patient	5.3	7.5
Number of recessions	97	141
Number of maxillary incisors	6	21
Number of maxillary canines	18	28
Number of maxillary premolars	22	39
Number of maxillary molars	11	23
Number of mandibular incisors	11	1
Number of mandibular canines	10	5
Number of mandibular premolars	12	17
Number of mandibular molars	7	7
Number of Miller Class I recessions	63	107
Number of Miller Class II recessions	30	33
Number of thin biotype sites	48	85
Number of thick biotype sites	45	55
Mean recessions (SD), mm	2.84 (0.79)	2.77 (0.84)
Percentage of thick biotype (SD)	0.32 (0.31)	0.31 (0.26)
Mean keratinized mucosa height (SD), mm	1.69 (1.14)	2.04 (0.92)
Mean probing pocket depth (SD), mm	1.62 (0.57)	1.81 (0.52)
Mean clinical attachment level (SD), mm	4.47 (1.12)	4.55 (1.07)

SD, standard deviation.

methods were applied, otherwise the analyses were performed parametrically. The two independent implant groups CTG and ADMA were compared in these values and in the differences yielded between each two points in time using the Mann-Whitney U test. Separately for both groups the three measurements over time were tested for significant change using Friedman's test with post-hoc analyses by Wilcoxon matched pair tests. Ordinally and nominally scaled values as the patients' assessment were displayed in absolute and percent frequencies. Two of each of these values were compared in contingency tables and tested for dependence with the chi-square test. If the expected frequencies turned out to be too small, the exact test according to Fisher was used. The tests were performed two-sided with a significance level of 5%. An alpha adjustment for multiple testing was not applied, and the results were interpreted accordingly. Statistical calculations were performed with SPSS Statistics v25 (IBM).



Table 2 Comparison of CTG and ADMA (Mann-Whitney U test)

Characteristic		T0	T6m	T5y	T6m-T0	T5y-T0	T5y-T6m
GR	CTG, mean (SD)	2.84 (0.79)	0.13 (0.16)	0.52 (0.65)	-2.71 (0.73)	-2.27 (0.77)	0.45 (0.62)
	ADMA, mean (SD)	2.77 (0.84)	0.61 (0.41)	0.92 (0.65)	-2.15 (0.67)	-1.82 (0.69)	0.35 (0.54)
	P value	.673	< .001	.077	.029	.227	.515
BIO	CTG, mean (SD)	0.32 (0.31)	0.93 (0.23)	0.84 (0.28)	0.61 (0.35)	0.51 (0.39)	-0.14 (0.30)
	ADMA, mean (SD)	0.31 (0.26)	0.89 (0.16)	0.63 (0.42)	0.58 (0.21)	0.33 (0.46)	-0.27 (0.40)
	P value	.905	.032	.163	.606	.190	.498
KM	CTG, mean (SD)	1.69 (1.14)	3.58 (1.40)	3.98 (0.89)	1.88 (1.60)	2.27 (1.02)	0.06 (1.16)
	ADMA, mean (SD)	2.04 (0.92)	3.08 (0.93)	3.06 (0.97)	1.04 (1.08)	1.14 (0.96)	-0.04 (1.11)
	P value	.361	.201	.010	.081	.010	.678
PPD	CTG, mean (SD)	1.62 (0.57)	1.60 (0.51)	1.16 (0.55)	-0.03 (0.45)	-0.42 (0.91)	-0.38 (0.87)
	ADMA, mean (SD)	1.81 (0.52)	1.54 (0.36)	1.19 (0.76)	-0.28 (0.62)	-0.55 (0.99)	-0.38 (0.84)
	P value	.254	.910	.691	.221	.637	.762
CAL	CTG, mean (SD)	4.47 (1.14)	1.73 (0.56)	1.68 (0.90)	-2.74 (0.99)	-2.70 (1.39)	0.07 (1.10)
	ADMA, mean (SD)	4.55 (1.07)	2.16 (0.56)	2.12 (1.20)	-2.39 (1.01)	-2.33 (1.37)	-0.05 (1.10)
	P value	.491	.029	.416	.298	.473	.521

ADMA, acellular dermal matrix allograft; BIO, gingival biotype; CAL, clinical attachment level; CTG, connective tissue graft; GR, gingival recession; KM, keratinized mucosa width; PPD, probing pocket depth; SD, standard deviation; T0, time of baseline examination; T6m, time of 6-month examination; T5y, time of 5-year examination.

Table 3 Statistical test results of change over time for CTG and ADMA

P values	Global test		T6m vs T0		T5y vs T0		T5y vs T6m	
	CTG	ADMA	CTG	ADMA	CTG	ADMA	CTG	ADMA
GR	< .001*	< .001*	< .001 [†]	< .001 [†]	.001 [†]	< .001 [†]	.011 [†]	.027 [†]
BIO	< .001*	< .001*	< .001 [†]	< .001 [†]	.002 [†]	.018 [†]	.063 [†]	.0192 [†]
KM	< .001*	< .001*	< .001 [†]	< .001 [†]	.001 [†]	< .001 [†]	.820 [†]	.407 [†]
PPD	.479*	.043*	NA	.064 [†]	NA	.038 [†]	NA	.036 [†]
CAL	< .001*	.002*	< .001 [†]	.001 [†]	.002 [†]	.001 [†]	.666 [†]	.776 [†]

ADMA, acellular dermal matrix allograft; BIO, gingival biotype; CAL, clinical attachment level; CTG, connective tissue graft; GR, gingival recession; KM, keratinized mucosa width; PPD, probing pocket depth; T0, time of baseline examination; T6m, time of 6-month examination; T5y, time of 5-year examination.

*Friedman test.

[†]Wilcoxon matched pairs test.

Results

The main baseline patient and site characteristics are presented in Table 1. Between the CTG and ADMA group there were no apparent significant baseline imbalances except the higher proportion of treated recessions per patient in the ADMA group (7.5 versus 5.3).

Considering the complications during or after surgery and during the whole follow-up period, there occurred only one minor event: 7 days after surgery (at sutural removal), one ADMA was exposed. Within the healing period the exposed dermis resorbed over time and the recession reduced from 4.0

to 2.5 mm. The long-term follow-up period showed no complications in both groups.

The main results for all outcome measures at the three examination times and differences between times comparing the CTG and ADMA group are summarized in Table 2.

Six months after surgery (T6m), the main outcome GR was statistically significantly reduced in both groups (CTG, 2.71 mm; ADMA, 2.15 mm). Regarding the mean, there was 0.48-mm less recession at CTG sites, which was statistically significant ($P < .001$). At the long-term follow-up (T5y), the mean recession in the CTG group was 0.52 mm, and in the ADMA group 0.92 mm, but the difference was not statistically significant

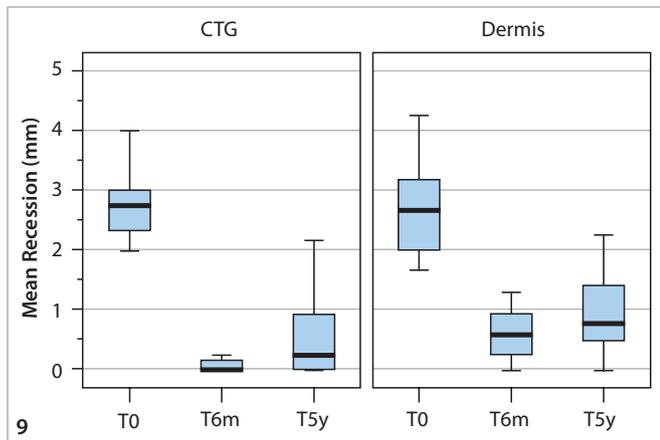


Fig 9 Mean gingival recession.

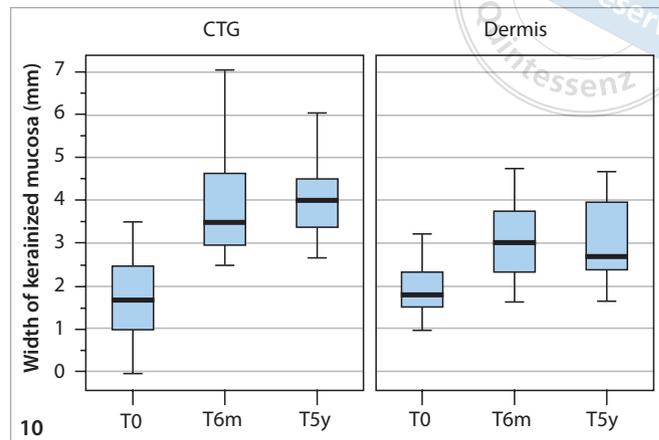


Fig 10 Width of keratinized mucosa.

($P = .077$) (Table 2 and Fig 9). Regarding the change over time, significant loss of root coverage was observed in both groups at the 5-year examination (Table 3).

Comparing the changes in the percentage of thick biotype (BIO) in both groups over time, there was no obvious difference after 6 months (CTG, 93%; ADMA, 89%). At the 5-year examination this reduced more in the ADMA group (63%) than in the CTG group (84%), without statistical significance ($P = .163$).

Regarding the increase in KM after 6 months (CTG, 1.88 mm; ADMA, 1.04 mm), there was no statistically significant difference ($P = .081$). However, at 5 years the CTG group showed a significantly higher dimension (3.98 mm) compared to the ADMA group (3.06 mm) ($P = .081$) (Table 2). These results were visualized in Fig 10.

Both procedures significantly improved in clinical attachment level (CAL) (on average 2.74 mm for CTG, and 2.33 mm for ADMA) after 6 months (Tables 2 and 3). These results stayed constant up to the 5-year follow-up without a significant difference between the two groups.

Neither the 6-month nor the 5-year measurements revealed significant changes for the PPDs between the groups (Table 2) and over time (Table 3) compared to baseline.

Discussion

The main goal of this trial was to compare the long-term outcome of two different grafts (ADMA and CTG) to be used for the covering of gingival recessions. The weakness of the study is the nonrandomized design due to the execution of the surgeries in a private practice. Allogeneic tissue substitutes are still

unusual in our clientele, requiring integration of the patients more in the decision process than would be possible with a randomized controlled trial (RCT). As it was a patient preference trial and the first 21 patients to choose one of the two treatment protocols were included in the study, there was no external influence in selection of the patients. The authors estimate the risk of bias equal to a regular RCT. Furthermore, Miller Class III and IV recessions were excluded due to their unpredictable treatment results and thus a higher risk of bias. On the other hand, three more patients dropped out because of this, increasing the risk of bias.

The results show that both procedures were able to improve the clinical parameters investigated in the study, and to more or less stabilize them over 5 years, though slightly better results were obtained using CTG. Regarding the main outcome, GR, the statistically significant better results for CTG at 6 months remained at the 5-year examination but, this time, without statistical significance. In contrast, the difference in KM was statistically significant at the long-term follow-up whereas the 6-month data showed no significance. It can be concluded that there was a period of maturation lasting longer than 6 months in the present patient population. This observation should be followed-up in further studies.

When comparing these results to those of similar trials, the present authors could identify 17 RCTs comparing another ADMA (Alloderm, BioHorizons) with autogenous CTG, and these are summarized in a systematic review.²⁹ Other than the trial from Moslemi et al,³⁰ all these summarized RCTs have a short-term follow-up period of 6 to 12 months. A meta-analysis by Gallagher and Matthews²⁹ did not show a statistically signif-



icant difference in mean GR changes and CAL changes. In contrast to the present data, they found a statistically significant difference in the gain of KM. The mean difference was 0.43 mm in favor of ADMA. However, there was substantial heterogeneity of those RCTs. Neither Gapski et al's meta-analysis³¹ nor Chambrone and Tatakis' systematic review³² could identify a clear advantage of one of those grafting methods. Up to now there are no RCTs available that compare directly the same ADMA used in the present investigation (Puros Dermis). Two split-mouth RCTs compared Puros Dermis to another ADMA (Alloderm) with no statistically significant difference in terms of GR, KM, CAL, or PPD.^{33,34} Regarding the long-term outcome, the present data could be compared to Moslemi et al's RCT,³⁰ even if they used another ADMA. In this study, the relapse of recession from 6 months to 5 years was not statistically significant ($P = .365$) between the CTG (0.7 mm) and ADMA (0.97 mm) group, which is similar to the present results. Moslemi et al³⁰ made similar observations to the present trial for stability of KM over time. From 6 months to 5 years, Moslemi et al's patients lost keratinized tissue in both groups, but significantly more in the ADMA group (−1.23 mm) than in the CTG group (−0.1 mm).

The limitations of the present study include the small sample size, the lack of randomization, the strict inclusion criteria, and the lack of color match evaluation of the grafted areas. Due to the private practice setting it was considered to be simpler to let patients choose the grafting method they preferred. Therefore, group allocation is a potential risk of bias. Though group allocation was not performed at random, all assessments were performed by a masked outcome assessor. Another limitation for the long-term outcome is that some of the patients were referred for root coverage procedures by general dental practitioners and went back for recall visits after the 6-month exam-

ination, so a standardized professional recall management cannot be guaranteed for all patients for the period between 6 months and 5 years. Also, the dropout of 7 patients between the 6-month and 5-year examination represents a certain limitation of this trial. For all the above reasons the present findings may not be generalized with confidence to other populations. It would be desirable to have more data in an RCT setting investigating the long-term outcome of the examined ADMA to gain stronger evidence for presurgical communication with the patient. ■

Conclusion

Regarding the long-term outcome, ADMAs could be an alternative treatment option to autogenous CTGs to cover GRs and increasing soft tissue thickness. If the gain of keratinized tissue is considered as a main goal, CTGs may have a slight advantage, while ADMAs may cause less postoperative pain.

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