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Cover Page Footnote

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Evaluation of Mucograft® in increasing the peri-implant soft tissue thickness in the esthetic zone.

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ABSTRACT

Objective: To study the effect of Collagen matrix Mucograft (CM) in enhancing the soft tissue thickness around immediate implants (II) in comparison to subepithelial palatal connective tissue grafts (SCTG).

Subjects & methods: This randomized, controlled clinical trial included 16 patients, who were randomly divided into test (IIP +CM) and control (IIP+SCTG) groups. Clinical parameters evaluated at baseline, 3-months, and 6-months were papillary bleeding index (PBI), gingival index (GI), facial probing depth (FPD), palatal probing depth (PPD). Direct measurements of gingival thickness were evaluated at baseline and 6-months follow up. Pink esthetic score (PES) and white esthetic score (WES) were evaluated at the end of the study.

Results: No statistical difference in the PBI (-0.156 ± 0.44) and GI (-0.175 ± 0.74) of the test group compared to the control group (0.484 ± 0.63) and (0.469 ± 0.59) respectively. On the other hand, there was reduction in the facial probing depth in control group (-0.056 ± 0.20) compared to the test group (0.351 ± 0.13). Direct measurement of the gingival thickness reflected an increase in the gingival thickness in both groups at 2, 4 and 6 mm from the free gingival margin (FGM). However, there was a significant difference in the average gingival thickness in favor of control group (0.493 ± 0.30) compared to the test group (0.215 ± 0.56). The PES/WES in the both groups were >7 showing a satisfactory esthetic result in all patients included in this study.

Conclusion: Improvement of the facial peri-implant soft tissue thickness can be achieved using soft tissue grafts. Palatal SCTG improved the gingival thickness around immediate implants better than CM. CM offered less patient morbidity, homogenous color with the surrounding soft tissue and shorter surgical time.

Keywords: Collagen matrix, immediate implant placement, esthetic zone, palatal subepithelial connective tissue graft, gingival thickness.

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Despite the great advancement of modern dentistry, loss of natural teeth for one reason or another is still present (1). Dental implants have become an effective and popular treatment option for replacing missing teeth with long-term survival rates reaching 95–

97% after a period of 5–10 years in function (2).

Immediate implant placement after extraction has been a reality for single-tooth implants since 1989, when Lazzara, placed

immediate implants in maxillary bicuspids(3).

Esthetic expectations related to dental implant therapy are increasingly demanding. This has been precipitated by the profession's shift from a focus on osseointegration to one on "esthetic-integration" of the alloplastic tooth replacement into the natural dentition (4). Success has been achieved with hard- and soft-tissue preservation and reconstruction as well as restorative material advancements (5) (6) (7).

Recent studies have advocated the use of subepithelial connective tissue graft from the palatal mucosa to augment the soft tissue and to increase the thickness and the overall resistance of the implant facial soft tissue to recession (8) (9) (10)

However, anatomic structures, such as the greater palatine artery, limit the size and amount of the obtained connective tissue (11). Complications, such as patient discomfort, post-surgical pain, paresthesia, and bleeding from the donor area, can occur if the artery is injured. In addition, obtaining connective tissue from the palatal area is technique sensitive for a general practitioner to perform. Therefore, an easier technique with fewer complications should be considered (12).

In order to avoid this patient morbidity, an alternative option is the use of collagen membranes of porcine origin, which are already standard in oral wound-healing procedures (13).

A new two-layer xenogenic collagen matrix (Mucograft®, Geistlich) has been proposed and seemed to indicate that the use of the new collagen matrix was a viable alternative to a subepithelial connective tissue graft, with

significantly lower patient morbidity (14) (15) (16) (17).

CM was developed with similar characteristics to the most used resorbable collagen membrane with an extra indication to further influence the healing cascade and reduces scar retraction in periodontal defects (18). In addition, it was designed to avoid autologous tissue harvesting and can act as free gingival graft (FGG), connective tissue graft (CTG), or dermal graft (DG) (19) (20).

Considering the promising properties of the CM, the present study aimed to evaluate its effect in enhancement of the peri-implant soft tissue thickness in IIP protocol and compare it to autogenous SCTG from both the palate and the tuberosity.

Subjects and methods

This study was carried out on 16 patients (4 males and 12 females) from the outpatients' clinic in faculty of Dentistry, Ain Shams University and faculty of oral and dental medicine, Future university in Egypt. The study protocol was approved by the ethical committee of the faculty of dentistry, Ain Shams University.

The patients were selected according to the following criteria:

Patients seeking extraction of hopeless upper anteriors and bicuspids, and insertion of immediate dental implants.

Patients' age range from 20-55 years.

Proper oral hygiene following initial non-surgical therapy.

The patient's capability to follow the study protocol and willingness to sign an informed consent form.

Patients having adequate soft tissue volume in both vertical and buccolingual directions with the biologic soft tissue height or width is 3 to 4 mm (21)(22). After extraction, only patients with type I extraction sockets were included in the study (23)

Patients free from any relevant systemic disease according to the modified Cornell medical index (24).

The criteria for exclusion were as follows:

Patients with history of systemic illness, drug abuse, catabolic drug or psychiatric disorder (25). Pregnant females were also excluded.

Patients having head and neck radiation treatment (26)(27) and patients allergic to the collagen (28).

Patients having insufficient bone quantity and also having insufficient vertical inter-arch space upon centric occlusion.

Patients with parafunctional habits such as bruxism or clenching that might produce overload on the placed implants(29) (30)

Patients with acute infection at tooth site (31)(32). Smokers and alcoholics were also excluded (33)(34).

All patients who participated in the study were informed about the surgical protocol and all the risks associated with the procedures and signed an informed consent form.

The data obtained from the patients as well as the follow-up results were kept confidential.

Pre-Surgical Evaluation:

Local visual examination and palpation to examine the entire oral and peri-oral tissues was carried out in addition to pre-surgical radiographic evaluation in order to detect the

presence of any clinically undetectable pathology. Maxillary and mandibular impressions were taken and poured into stone to check the occlusion and direction of forces in respect to the future implant site. Presurgical phase 1 periodontal treatment was performed to all patients prior to implant placement.

Surgical Protocol

After administration of local anesthesia, the teeth were extracted atraumatically using periostomes and followed by forceps. A great care was applied to preserve the socket walls during extraction, particularly the labial/buccal wall, the level of which it was harmonized with that of neighboring teeth to ensure esthetic emergence of prosthetic post. Careful curettage and alveolar cleaning was made to remove any trace of infected or granulated tissue together with remains of the periodontal ligament (35)(36). Periodontal probe was used to check the integrity of the socket walls and a full-thickness envelope flap was created between the facial bone plate and the overlying gingiva (37).

Drilling of the socket was done at an angle to the socket wall and the implant (Osteoseal Co. 51 Dupont Drive, Irvine, 92696, CA, USA). was placed in a more palatal position (38) to avoid any pressure on the labial bone plate. All osteotomy sites included in the study showed the absence of any bone wall fenestrations or dehiscence. When found, the patients were excluded from the study and socket preservation procedure was carried out.

Following the implant placement, healing abutments were screwed to the implants. oft tissue grafts were inserted into the prepared envelope and secured with 5.0 chromic gut

suture (Figure 1). Light pressure was applied over the flap with moist gauze for 10 minutes to diminish blood clot between the graft and the underlying bone (39).

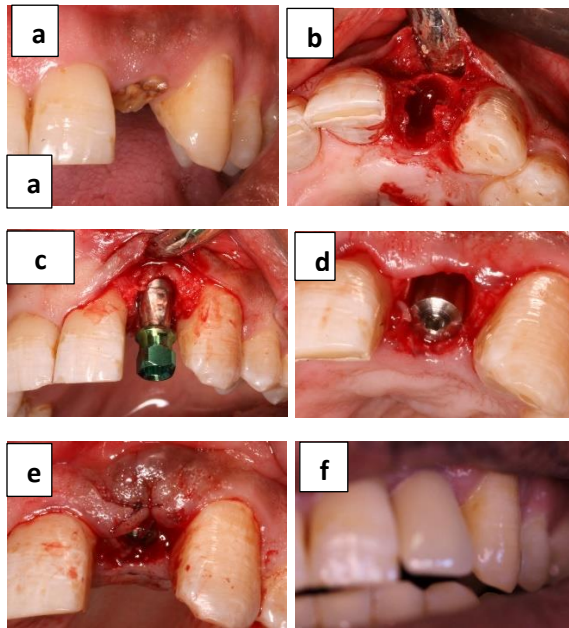


Figure1 Representative clinical pictures of the surgical procedure. (a) presurgical picture showing badly decayed upper lateral incisor. (b) the extraction socket with preserved labial plate of bone. (c) implant placement. (d) placement of healing abutment. (e) suturing of the flap. (f) 6-months follow-up after placement of the prosthetic crown.

Sixteen patients were divided into two groups:

1. Control group with 8 patients received immediate implants and autogenous SCTG harvested from the palate using the single-incision palatal harvest technique(40) and placed in the prepared envelope flap (Figure 2).

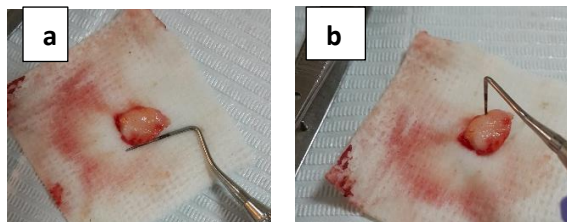


Figure2 Representative clinical picture showing the palatal SCTG (a) measuring the length of the SCGT graft. (b) measuring the thickness of the SCGT.

2. Test group with 8 patients received immediate implants and Porcine Collagen Matrix (Geistlich Mucograft® , Geistlich Pharma AG, Wolhusen, Switzerland) placed in the prepared envelope flap (Figure 3).

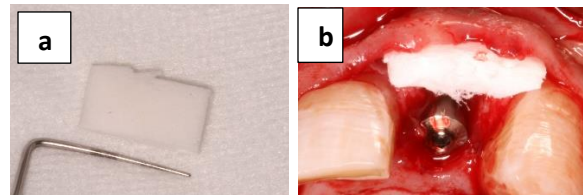


Figure3 Representative picture of the test case. (a) showing trimming of the graft to the adequate size. (b) placement of the graft in the prepared envelope flap.

Post-surgical medications and instructions:

Oral hygiene instructions were given to the patients and antibiotics Amoxicillin 875 mg and Clavulanic acid 125mg (Augmentin, 1 gm (Medical Union Pharmaceuticals, Egypt, for: GlaxoSmithKline).) twice daily for 7 days) were prescribed to prevent post-operative infection (41)(42). Ibuprofen 600 mg/8h/3day (Brufen, 600mg Kahira Pharm. & Chem. Ind. Co., Egypt). was prescribed to act as an anti-inflammatory and analgesic (43). Patients were advised to rinse with 0.12% chlorohexidine gluconate (Antiseptol mouth wash Kahira Pharm. & Chem. Ind. Co., Egypt) solution twice a day, for 2 weeks (9). In addition, patients were instructed to minimize trauma to the surgical site, to clean the healing abutments with ultrasoft toothbrush(44) and to keep on soft diet for 2 weeks following the surgery. Sutures were removed after one week and soft tissues were allowed to mature for 3 months before placing the definitive restoration (45) (46).

Prosthetic phase:

After a healing period of 3 months, a screw-retained transfer coping was connected to the implant and impressions were taken using polyvinyl siloxane material for construction of the final porcelain fused to metal restoration. The final restorations were checked for shade matching, marginal fitness and occlusion then cemented using calcium hydroxide cement. The occlusion on the prosthesis was designed to minimize force distribution to the adjacent teeth (47).

Postoperative follow-up and evaluation:

All patients were evaluated after 2 weeks, 1, 3 and 6 months postoperatively. In addition, they were participated in a supportive periodontal treatment including periodontal debridement, root planing and polishing. At the 6-month visit, all patients were asked about their satisfaction with the esthetic outcome of the implant and the changes in the soft tissue around the implants.

Clinical evaluation:

Clinical evaluations of papillary bleeding index (PBI) (48), gingival index (GI)(49), labial & palatal probing Depth (PD)(50), were obtained at baseline (BL) (before tooth extraction & IIP), 3 and 6 months following IIP. White esthetic score (WES) and pink esthetic score (PES)(51) were obtained at 6 months follow up.

In addition, direct measurement of the facial gingival tissue thickness using an endodontic file with stopper, which was placed horizontally, perpendicular to the long axis, at 2, 4 and 6 mm from the free gingival margin were taken at BL and at 6 months follow up (Figure 4).

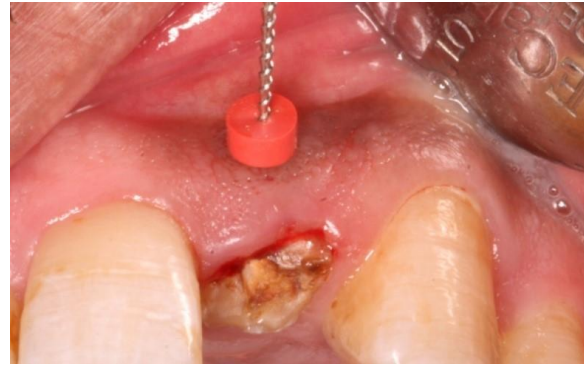


Figure4 Representative picture showing the measuring of the gingival thickness using the endodontic file.

Statistical analyses:

Quantitative data were expressed as mean and standard deviation. Statistical analysis was performed using SPSS software (Statistical Package for Social Sciences version 20.0, IBM SPSS®, Chicago, IL, USA). The level of significance (α error) was considered as 5% and p-value < 0.05 was considered significant for interpretation of results. Descriptive and analytical statistics were done. The paired and unpaired Student's t-tests were used to check differences between the groups during follow-up evaluation.

Results:

In the present study, 80 patients were screened for inclusion criteria. A total of 64 patients were excluded from the study. sixteen patients with badly decayed upper anterior tooth and satisfying the other inclusion criteria were then selected for the study. Out of 16 patients, 4 males and 12 females with a mean age of 36.66 (± 10.36) years participated and completed the study.

Wound healing was favorable with no signs of post-operative complications of significance in both the groups. None complained of extreme post-operative pain,

hemorrhage, illness, tiredness, etc. None of the patients reported with any wound opening of the treated sites, post-operative swelling intraorally or extra-orally.

All the patients attended follow-up appointments regularly and maintained proper oral hygiene as established by statistically significant lower plaque index and papillary bleeding index scores after 3 and 6 months compared to baseline (Table 1).

Table1 Mean ±SD of PBI, GI, FPD and PPD in control and test groups

	Control	Test	P-value
PBI			
0-3	-0.125 ±0.37	0.625 ±0.68	0.02 [†]
3-6	-0.031 ±0.28	-0.141 ±0.35	0.499 [†]
0-6	-0.156 ±0.44	0.484 ±0.63	0.036 [†]
P-value	0.351 [†]	0.067 [†]	
GI			
0-3	-0.269 ±0.77	0.280 ±0.46	0.11 [†]
3-6	0.094 ±0.03	0.189 ±0.67	0.701 [†]
0-6	-0.175 ±0.74	0.469 ±0.59	0.076 [†]
P-value	0.267 [†]	0.061 [†]	
FPD			
0-3	0.043 ±0.61	0.664 ±0.74	0.089 [†]
3-6	-0.099 ±0.25	-0.313 ±0.37	0.2 [†]
0-6	-0.056 ±0.20	0.351 ±0.13	<0.001*
P-value	0.791 [†]	0.036*	
PPD			
0-3	-0.084 ±0.75	0.604 ±0.11	0.036 [†]
3-6	0.094 ±0.30	-0.219 ±0.13	0.023 [†]
0-6	0.010 ±0.17	0.385 ±0.05	<0.001*
P-value	0.954 [†]	0.0002*	

*Statistically significant difference at p-value < 0.05

[†]Statistically non-significant difference at p-value > 0.05

At baseline, clinical direct measurement of the gingival thickness (DGT) was done on the facial surface of the unrestorable teeth at 2, 4 and 6 mm from the free gingival margin. After 6 months, there was significant increase in the average gingival thickness around the dental implant in the control group, where it showed a gain of 0.447± 0.04 mm. On the other hand, test group showed insignificant

increase in the average gingival thickness of 0.122 ± 0.06mm (Table 2).

Table2 Mean ±SD of direct measurement of gingival thickness at 2, 4 & 6 mm from the free gingival margin in addition to the average increase at baseline (BL) and 6 months follow up.

	Control	Test	P-Value
2mm			
BL	1.323 ±0.27	1.355 ±0.23	0.802 [†]
6-months	1.965 ±0.19	1.645 ±0.39	0.07 [†]
BL-6months	0.634 ±0.34	0.290 ±0.16	0.0214*
	P = 0.001*	P = 0.0025*	
4mm			
BL	1.474 ±0.60	1.163 ±1.60	0.6147 [†]
6-months	1.690 ±1.51	1.560 ±0.71	0.8288 [†]
BL-6months	0.216 ±0.61	0.398 ±0.61	0.5602 [†]
	P = 0.354 [†]	P = 0.109 [†]	
6mm			
BL	1.309 ±0.56	1.346 ±0.59	0.8995 [†]
6-months	1.801 ±0.47	1.131 ±0.32	0.0049*
BL-6months	0.493 ±0.30	-0.215 ±0.56	0.0071*
	P = 0.003*	P = 0.316 [†]	
Average			
BL	1.365 ±0.38	1.28 ±0.31	0.6316 [†]
6-months	1.812 ±0.49	1.44 ±0.37	0.1086 [†]
BL-6months	0.447 ±0.04	0.122 ±0.06	<0.0001*
	<0.0001 *	0.0906 [†]	

*Statistically significant difference at p-value < 0.05

[†]Statistically non-significant difference at p-value > 0.05

At 6 months, the mean of WES was 7.12 ± 1.88 and 7.00 ± 1.06 in the control and test groups respectively showing no statistical difference between the two groups. In addition, there was no significant difference in the PES between the two groups; however, the control group 7.62 ± 0.62 was superior to the test group 7.00 ± 1.77.

Discussion:

Immediate implant placement (IIP) offers feasible advantages for both clinicians and patients in terms of evident economic and social impact of a reduction in the number of surgeries, treatment time and patient satisfaction (52).The esthetic outcome is usually obtained by healthy established peri-

implant tissues as well as the fabricated implant crown (53).

The choice of the palatal SCTG in the present study was due to the fact that the greatest amount of connective tissue exists primarily in the palatal area of the maxilla (11). The thickness of the palatal masticatory mucosa ranges from 2 to 5 mm and varies according to the position in the dental arch (54)(55). The thickness of the SCTG is an important factor for obtaining optimal esthetics where a 1.5- to 2-mm thickness is needed to preserve vascularization, promote wound healing, and provide long-term graft stability(54)(56)(12).

Over the past decade, different biomaterials, such as barrier membranes and biologic modifiers, have been investigated (57)(58). The collagen matrix (CM) (Mucograft®) is composed of non-crosslinked porcine collagen with a dense outer layer intended to protect the wound and an inner layer that is porous to allow the ingrowth of tissue (59)(60).

Only patients with Type I sockets were included in this study since this socket requires no augmentation procedure and could be treated with an immediate implant approach with expected satisfactory results according to Elian et al. 2007(23).

The results of this study showed an increase in both papillary bleeding index (PBI) and gingival index (GI) score in test group after 6 months follow up. However, this increase was insignificant. On the other hand, the obtained results from control group showed insignificant reduction in both PBI and GI. These results may indicate more favorable tissue reaction towards autogenous grafts than towards CM.

After 3 months, the results concerning the clinical measurements showed a clinically and statistically significant increase of facial probing depth (FPD) in test group, while the increase in FPD was insignificant in control group. After 6 months the clinical measurements showed an improvement in the form of reduction of FPD in control group (-0.056 ± 0.205). In contrast, test group expressed significant increased FPD (0.351 ± 0.136).

Concerning the changes in the palatal probing depth (PPD), there was an increase in the palatal probing depth (PPD) in both groups, however this increase was insignificant in control group (0.010 ± 0.171) and significant in test group (0.385 ± 0.052). This increase could be related to the crestal bone loss that occurs after IIP.

At baseline, clinical direct measurement of the gingival thickness (DGT) was done on the facial surface of the unrestorable tooth at 2, 4 and 6 mm from the free gingival margin. After 6 months, there was significant increase in the average gingival thickness around the dental implant in the control group, where it showed a gain of 0.447 ± 0.04 mm. On the other hand, test group showed insignificant increase in the average gingival thickness of 0.122 ± 0.06 mm.

The results obtained from control group go in accordance with Grunder 2011(61) and Eghbali et al. 2016 (62) who reported absolute mucosal thickness gain of 0.34 and 0.83 mm after 6 and 9 months respectively following SCT grafting around implants. However, the results were clearly lower when compared with those obtained by Speroni et al. 2010 (63) and Wiesner et al. 2010 (64) who gained after 12 months 1.75 and 1.20mm

respectively, and Cairo et al. 2017 (65) who gained 1.2mm after 6 months.

Disparity in the results may be due to differences in the initial need for tissue augmentation, timing of tissue augmentation, surgical techniques, evaluation periods, assessment points and tooth locations.

Regarding test group, the gain in the gingival thickness was significantly less than that obtained in control group. Accordingly Cairo et al. 2017 (65) compared between CM and SCTG in increasing the gingival thickness around immediately placed implants and reported significant difference in favor of the palatal SCTG group.

However, the acquired results in test group were obviously less than similar studies that reported gain in the GT ranging from 0.7mm to 0.9 mm (13)(66)(65). This difference could be related to different surgical techniques as Froum et al. 2015(13) used a full-thickness flap with incisions extending beyond the MGJ, and Schallhorn et al. 2015 (66) used split-thickness pouch technique, while in this study a full-thickness envelope technique was applied. Another cause of the diversity in the obtained results is the layering of the applied CM. Cairo et al. 2017(65) applied double layer of CM with 6 mm final thickness outcome, while in the present study single layer of CM was applied. Different measuring points may also play a role in the variety of the obtained measurements.

In this study there was a reduction in the gingival thickness at 6mm distance from FGM (- 0.215). Schallhorn et al. 2015(66) mentioned that although CM produced a statistical significant increase in the gingival thickness around implants, the results in the implant sites were variable where some were

only marginally improved while others achieved soft tissue thickness and keratinized tissue thickness up to 2 mm.

Regarding the present study, after 6 months the superior PES was expressed by the control group. This result goes in accordance with Cosyn et al. 2011(67) who proposed that a PES score of < 7 was used to define esthetic failure, which means that the obtained results in this study considered as acceptable with favorable esthetic outcomes.

No statistically significant difference was found between the 2 groups regarding the WES. The results were in accordance with Kolerman et al. 2016 (68) who reported a WES of 7.3, while they were lower than Migliorati et al. 2013 (69) who obtained a WES of 7.9. In addition, Khzam et al. 2015 (70) reported a mean WES > 7 in the included studies in their systematic review which means that the obtained results in this study guarantee acceptable esthetics.

The main goal of the present study was to enhance the gingival thickness and soft tissue profile after IIP. Autogenous palatal grafts aided in a more increase of the gingival thickness than CM. The successful application of autogenous SCTGs in plastic periodontal and implant surgery might be explained as SCTGs have the characteristics of the ideal soft tissue graft with exhibiting an optimal potential for tissue specific conduction and induction and containing the largest number of transplanted vital cells. In addition, the chances that a large number of living fibroblasts in the graft will survive (tissue-genetic potential) and continue to produce tissue-specific endogenous proteins (tissue-inductive properties) by receiving a sufficient supply of nutrients and oxygen

quickly enough appear to be relatively good (71).

Meanwhile, CM was also relatively successful in increasing and improving the gingival thickness on the facial surface of immediate implants. Moreover, it should be taken into consideration the added advantages of using CM in terms of less tissue morbidity and reduction of the surgical time observed in this study when compared to autogenous grafts. Furthermore, patients in the CM group reported less pain and less use of analgesics following the surgical procedure which is an important aspect to be well thought-out when planning the surgical technique to be used.

Recommendations:

Larger sample sizes with prolonged follow up periods are required to observe the changes in the gingival thickness around immediate implants following soft tissue grafting.

The correlation between the socket facial bone thickness and the dimensional changes in the bony ridge should be investigated

Comparing between immediate and delayed loading of the immediate implants in terms of improving the soft tissue profile.

Investigating if the application of bone grafts in immediate implant procedure in addition to soft tissue grafts will aid in better preservation of the bone and soft tissue.

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