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Preliminary Report

Tissue Contraction With Helium-Based Plasma Radiofrequency Technology: A Preliminary Report of Initial Ultrasound Findings

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Abstract

Background: Application of helium-based plasma radiofrequency (RF; Renuvion, Apyx Medical, Clearwater, FL) in the subcutaneous plane results in tissue coagulation and contraction. Although, traditionally, the impact of thermal devices on skin laxity is assessed by measuring changes in skin surface area, this indirect measure does not permit intraoperative assessment or differentiation of effects from various treatments.
Objectives: To determine the amount of soft tissue contraction achieved by multiple passes of helium plasma RF energy to the subcutaneous connective tissues following power-assisted liposuction (PAL).
Methods: In this single-center study, 4 patients were assessed using real-time ultrasound measurements at baseline and following both PAL and each pass with helium plasma RF.
Results: Based on changes in the distance from the skin (dermal basement membrane) to Scarpa's fascia, PAL produced an average reduction of 36.7% (standard deviation [SD] 14.6; range, 24.7%-58.6%) because of the fat removal. Contraction observed with helium plasma RF was greatest for the first pass, with a mean decrease of 27.0% (SD 19.6; range, 4.5%-52.1%) in distance relative to distance measured following liposuction. Subsequent passes resulted in additional incremental contraction relative to previous treatment pass: 17.0% (5.1) for Pass 2, 7.7% (17.5) for Pass 3, and 7.1% (5.5) for Pass 4. Overall, helium plasma RF resulted in an average contraction of 44.0% (SD 17.2; range, 27.1%-59.4%) in the skin-to-Scarpa-fascia measurement.
Conclusions: Helium plasma RF improved tissue contraction following PAL by an average of 44%, and data suggest that the greatest increase in tissue contraction is obtained by the first treatment pass.

Level of Evidence: 5 (Therapeutic)

When helium-based plasma radiofrequency (RF; Renuvion, Apyx Medical, Clearwater, FL[1]) is applied in the subcutaneous space, the heat generated as the device is passed through the subcutaneous septal network results in protein coagulation and contraction of connective tissue of the stromal matrix.[2] This contraction draws the skin closer to the underlying muscle, thereby improving the appearance of the skin and reducing its laxity. Traditionally, the impact of thermal devices on skin laxity has been assessed by measuring skin surface area.[3-7] Although surface area is informative, it is an indirect measure with important limitations. First, the stromal matrix connects Scarpa's fascia, Camper's fascia, and the dermis together with a loose interwoven network of collagenous tissue that is primarily in the *z*-axis (the distance from the skin to Scarpa's fascia) rather than the *x*- and *y*-axes. Thus, skin surface contraction measurement is a surrogate for contraction in the *x*- and *y*-axes, but does not take into account the *z*-axis, where the greatest amount of contraction occurs. In

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contrast, ultrasound measurements of the distance between the skin and Scarpa's fascia are direct measurements of the *z*-axis contraction caused by helium plasma RF. In addition, surface imaging does not permit real-time assessment or assessment of intraoperative changes, necessitating split-body studies to differentiate results of multiple procedures. In the study presented here, ultrasound was used to measure intraoperative debulking resulting from liposuction as well as tissue contraction resulting from multiple passes with helium plasma RF. This methodology permits direct measurement of treatment impact in the intraoperative setting and, here, allows for determination of the additive effects of helium plasma RF when combined with power-assisted liposuction (PAL). The objective of this study is to determine the amount of soft tissue contraction achieved by multiple passes of helium plasma RF energy to the subcutaneous connective tissues following PAL.

METHODS

Study Design

This single-center prospective study enrolled 5 patients who planned to undergo treatment with helium plasma RF following PAL in the abdomen. This study included both male and female patients, 18 to 65 years of age, who had a BMI of <35 kg/m^2. Patients could also undergo concomitant treatment in other areas as long as it did not interfere with measurements taken for the abdomen. This study took place beginning in May 2023 and is expected to conclude in October 2024. The helium plasma RF device used (Renuvion) is cleared by the United States FDA for the subcutaneous delivery of RF energy and/or helium plasma where coagulation/contraction of soft tissue is needed, and more specifically for use in the neck and submental area to improve the appearance of lax skin and in the body for aesthetic body contouring.[1] Thus, the use described here is consistent with device labeling.

Within this single-center study, ultrasound measurements of the abdomen were collected intraoperatively by a single ultrasound operator using a Versana Active 1.5 ultrasound (GE HealthCare, Chicago, IL). Measures were taken before treatment, after the application of tumescence, after liposuction, and following each treatment pass with helium plasma RF. Distances measured include the distance from the skin (the dermal basement membrane) to Camper's fascia, the distance from Camper's fascia to Scarpa's fascia, and the entire distance from the skin to Scarpa's fascia. Here, the classical definition of Scarpa's fascia was used, with Camper's fascia as the more superficial layer, intercalated in the adipose tissue, and Scarpa's fascia the deeper, membranous, and fibrous layer.[8-12] Consistent landmarks were used for each patient to ensure measurement at the same location across time points. All measurements were calculated from ultrasound images by an experienced ultrasonographer. Although measurements were also taken from the skin to Camper's fascia and from Camper's fascia to Scarpa's fascia, the analysis here focuses primarily on the overall direct measurement taken from the skin to Scarpa's fascia. During the procedure, patients were monitored for adverse events.

This interim analysis is part of a larger study that will include follow-up photographs and ultrasound images out to 1-year posttreatment, along with measures of global aesthetic improvement and patient satisfaction to assess tissue contraction over time as well as its relationship to aesthetic outcomes and patient experience.

This study was approved by Sterling IRB (Atlanta, GA). All study procedures were conducted in accordance with the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards.

Primary Outcomes

The analysis presented here includes study demographics, procedure information, and the total amount of connective tissue contraction produced by each helium plasma RF treatment pass. Ultrasound was also used to quantify the debulking resulting from liposuction. In addition, the relationship between tissue contraction and energy delivered was assessed, as well as the relationship between the postliposuction skin-to-Scarpa's fascia distance and overall percentage of tissue contraction achieved with helium plasma RF. Percentage change in distance from preprocedure and postliposuction distances was calculated as well as percentage change from previous pass with helium plasma RF.

Operative Technique

Following PAL, helium plasma RF energy was applied to the subcutaneous tissues to achieve tissue contraction. The same incisions used for liposuction were used for the helium plasma RF probe. The BPS-15 or BPS-27 handpiece was used in all cases, and the device power used was 85%, and helium flow was 2 L/min. The number of passes varied based on the judgment of the treating physician as well as the amount of energy delivered. Following treatment, excess helium was expressed. For the first patient, the helium was not adequately expressed, compromising the measurements taken, and the patient was excluded from the helium plasma RF dataset. Pre- and postprocedure care were based on the treating physician's standard of care, which included compression garments for 4 weeks postprocedurally along with routine postoperative visits in the clinic to assess their recovery.

RESULTS

Study Demographics and Procedure Data

Demographic and procedure information is shown in Table 1. Of the 5 patients enrolled, 4 were females and 1 was male. The mean patient age was 44 years (range, 34-53 years). Helium plasma RF treatment settings were 85% power and 2 L/min of helium flow and included an average (standard deviation [SD]) of 4.2 (1.1) antegrade/retrograde passes (range, 3-6) and 25.7 kJ (9.9) of energy delivered (range, 13.6-40 kJ). All patients included in the analysis received at least 4 passes, with 1 patient receiving 6 passes. All patients in the analysis were Caucasian.

Outcomes

Based on changes in the distance from the skin to Scarpa's fascia, PAL was shown to produce an average reduction of 36.7% (SD 14.6; range, 24.7%-58.6%) because of the removal of fat (Figure 1). The patient with the smallest decrease also had the lowest BMI. The amount of tissue contraction observed for helium

Table 1. Patient Demographics and Treatment Characteristics

Patient characteristic	Sex Female/male	Age	BMI (lb/in2)	Volume of fat removed (cc)	No. of passes	Energy (kJ)
Patient 1	F	54	24.55	800	6	20
Patient 2	F	49	29.66	1100	4	28.6
Patient 3	M	37	33.63	1900	4	40
Patient 4	F	34	36.61	2425	4	26.2

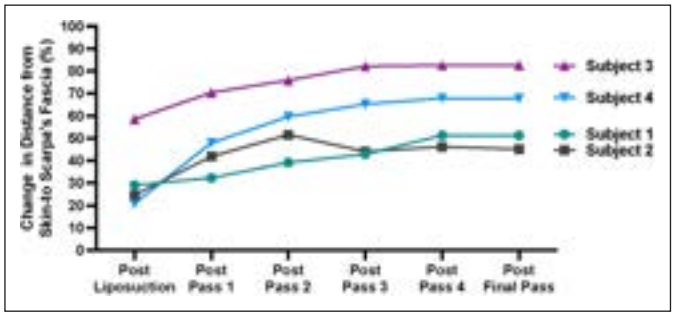

Figure 1. Tissue contraction observed based on percent change in distance from the skin to Scarpa's fascia from preprocedure baseline measures. Percentage decrease in distance because of debulking is shown for liposuction as well as decrease in distance because of tissue contraction following each pass with helium plasma radiofrequency, as well as for the cumulative change in distance following all treatment passes relative to preprocedure baseline measures.

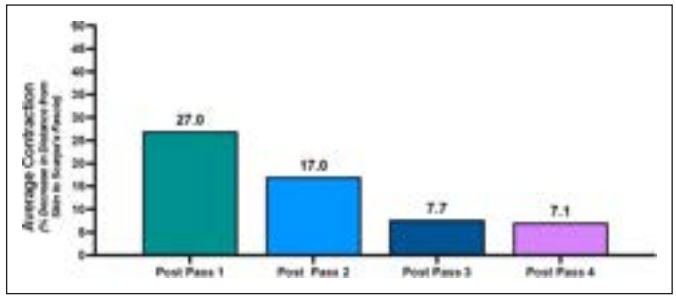

Figure 2. Incremental decreases in tissue contraction observed for each helium plasma radiofrequency treatment pass. Percentage change was calculated by comparing posttreatment distance from the skin to Scarpa's fascia to that for the previous treatment. For example, the percentage change in distance after Pass 1 is the incremental change compared with the distance measured after power-assisted liposuction, and the percentage change in distance after Pass 2 is the incremental change compared with the distance measured after Pass 1.

plasma RF relative to preprocedure baseline distance is shown in Figure 1.

The amount of contraction observed with helium plasma RF for the first treatment pass was calculated using post-PAL skin-to-Scarpa's-fascia measurements as the new baseline measure. For subsequent passes, percent change in distance was calculated using distance measured for the previous treatment pass as the new baseline. The change in distance was greatest for the first treatment pass, with an average decrease of 27.0% (SD 19.6; range, 4.5%-52.1%). Subsequent passes resulted in additional contraction, albeit to a lesser degree, with an average (SD) additional incremental contraction of 17.0% (5.1) for Pass 2, 7.7% (17.5) for Pass 3, and 7.1% (5.5) for Pass 4 (Figure 2). Overall, helium plasma RF resulted in an average contraction of 44.0% (SD 17.2; range, 27.1%-59.4%) in the post-PAL skin-to-Scarpa-fascia measurement. Ultrasound images showing changes in tissue contraction are shown in Figure 3.

The data also suggest that there is a correlation between the preprocedure skin-to-Scarpa-fascia distance and the percentage of intraoperative contraction observed, with smaller preprocedure measurements associated with less contraction (Table 2). This greater amount of contraction is accompanied by an increase in BMI. Higher BMI patients have a larger skin-to-Scarpa distance at baseline and thus a greater potential for contraction. In addition, a possible correlation between the total amount of energy delivered and the amount of intraoperative contraction was observed, with higher energy delivery resulting in greater contraction in most cases (Table 3); however, there does not appear to be a relationship between energy density delivered and contraction.

Safety Outcomes

No adverse events were observed during the intraoperative period assessed in this interim analysis.

DISCUSSION

Taken together, these results confirm that helium plasma RF results in intraoperative tissue contraction following PAL. Overall, the mean contraction percentage following treatment with helium plasma RF was 44.0% (SD 17.2; range, 27.1%-59.4%) relative to postliposuction measures, a decrease beyond the 36.7% (SD 14.6; range, 24.7%-58.6%) reduction in skin-to-Scarpa's fascia observed for liposuction compared with baseline, which is related to debulking. The 44% observed is consistent with studies demonstrating that collagen can shrink to between one-third and one quarter of its original length upon heating at 65 to 70 °C, respectively. This ~65% to 75% shrinkage is both time and temperature dependent. Of note, most of our current understanding of collagen shrinkage is based on in vitro experiments: in the clinic, in vivo collagen shrinkage is affected by surrounding tissues and other factors.[13] Importantly, the contraction percentage observed appears to be related to baseline skin-to-Scarpa-fascia measurement, and patients with larger measurements (and greater BMI) tend to have greater decreases in distance because of the increased capacity for contraction (Table 2). Although a possible positive correlation between total energy delivered and total intraoperative contraction was observed, this relationship appears to be restricted to total energy delivered rather than to energy density (Table 3).

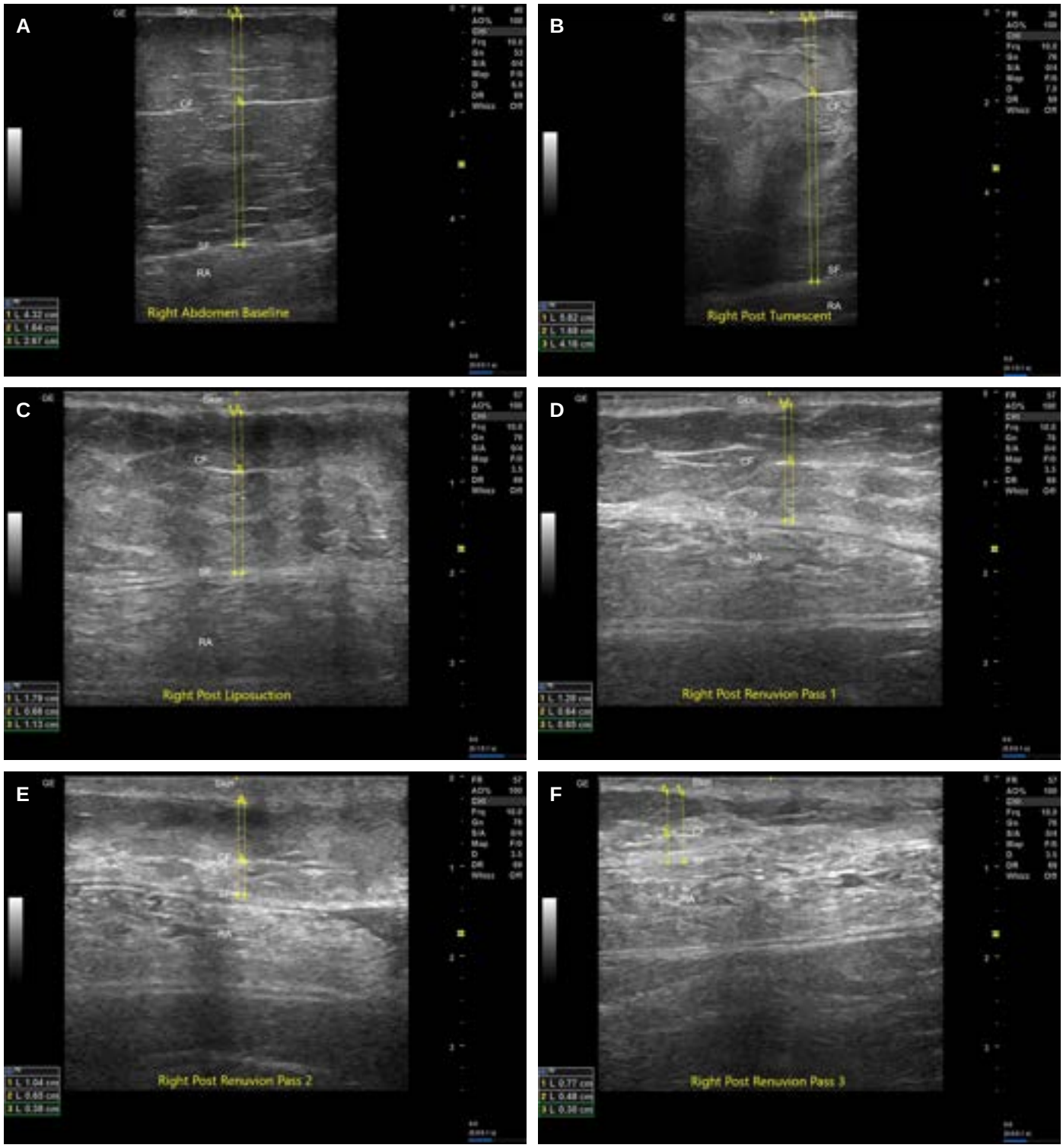

Figure 3. Example ultrasound images showing the change in the right abdomen: baseline (A), after tumescent (B), after liposuction (C), and after helium plasma radiofrequency Pass 1 (D), Pass 2 (E), Pass 3 (F), and Pass 4 (G). Camper's fascia (CF), Scamper's fascia (SF), and the rectus abdominis muscle (RA) are labeled.

The use of ultrasound, rather than surface imaging, allowed for real-time assessment of tissue contraction, and we were able to measure the impact of individual helium plasma RF treatment passes. The amount of contraction was greatest with the first pass (27.0%) compared with the following passes, which achieved incremental levels of contraction ranging from 7.1% to 17%. This greater amount of contraction for the first pass and incremental improvement thereafter is expected, as during the first treatment pass, there is no previously

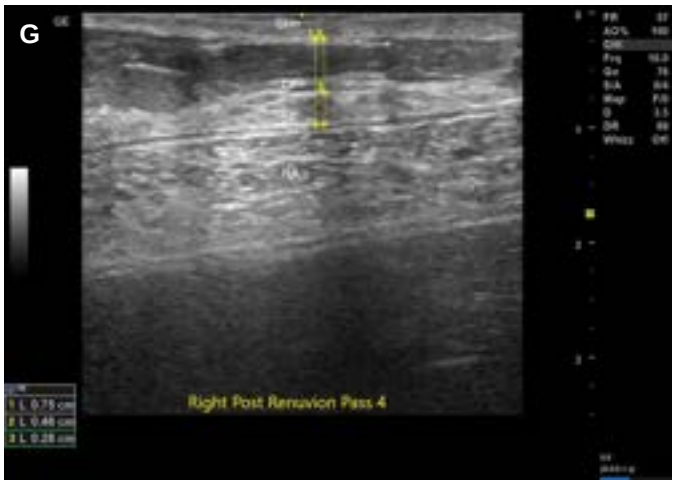

Figure 3. Continued

Table 3. Intraoperative Contraction and Energy Delivered

	Energy delivered (kJ)	Energy density (kJ/cm^2)	Total percentage change in distance from skin to Scarpa's fascia (post-PAL to final treatment pass) (%)
Patient 1	28.6	57.2	−59.4
Patient 2	20.0	41.4	−31.3
Patient 3	26.2	31.0	−27.1
Patient 4	40.0	33.1	−58.1
Average ± SD	28.7 ± 8.4	40.7 ± 11.9	−44.0% ± 17.2

PAL, power-assisted liposuction; SD, standard deviation.

treated subcutaneous tissue in the treatment area. As the device is used, the electrode moves rapidly, instantly heating surrounding tissues to temperatures >85 °C, a temperature at which only 0.04 s is needed for complete protein coagulation.[2,14,15] As a result, any tissue that the helium plasma beam comes into contact with will instantaneously contract to maximal levels. With each subsequent treatment pass, when the plasma beam encounters tissue that has been treated by previous treatment passes, the higher impedance of previously treated tissues will result in the plasma beam producing much less contraction of the previously treated tissue or diversion to adjacent untreated tissues with lower impedance. Either of these responses will result in less incremental contraction in comparison with the previous treatment pass. The decreasing contraction from helium plasma RF observed here suggests that the majority of the tissues in the stromal matrix have been treated by the first pass. Because only a single patient received >4 passes, it is impossible to say without further study whether additional passes beyond 4 would be equally as effective and would continue to result in further ~7% improvement or whether the percentage of improvement would be diminished.

The limitations of this study include the small number of patients and the limited number of patients who received >4 passes. Future studies will be needed to make a definitive statement about the degree of additional contraction expected for each treatment pass

Table 2. Intraoperative Contraction Following PAL

	Preprocedure distance from skin to Scarpa's fascia (cm)	Percentage change in distance from skin to Scarpa's fascia (post-PAL to final treatment pass) (%)[a]
Patient 1	0.93	−27.1
Patient 2	1.89	−31.3
Patient 3	2.77	−59.4
Patient 4	4.32	−58.1
Average ± SD	2.48 ± 1.44	−44.0% ± 17.2

PAL, power-assisted liposuction; SD, standard deviation. [a]Percentage change was calculated from distance following the final pass of helium plasma radiofrequency treatment compared with the distance following liposuction.

with helium plasma RF. These interim data are part of a longer term study that will be able to define the duration of effect; however, the interim data presented here are not able to offer information on the duration of skin contraction over time. The final data for this study will be helpful in determining whether subcutaneous stromal matrix contraction is maintained 1 year postprocedure as well as whether the degree of contraction observed is associated with global aesthetic improvement or patient satisfaction. A larger study would be helpful for confirming these results and could potentially identify any subgroup effects or patient features that impact response.

CONCLUSIONS

This study indicates that helium plasma RF provides additional tissue contraction following PAL of an average of 44% following 4 passes. This study also demonstrates that ultrasound is a viable tool for assessing intraoperative effects on the fascia and for differentiating the effects of multiple treatments on tissue coagulation.

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Disclosures

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