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Original Research Article

Efficacy and safety of SilverNova™ skin cream in post-aesthetic skin procedures

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ABSTRACT

Background: The objective of this study was to evaluate the efficacy and safety of SilverNova™ skin cream composed of SilverSol® (a patented colloidal nano silver technology from American Biotech Labs, USA) with other skin rejuvenators (coconut oil, vitamin E, and hyaluronic acid), in post-aesthetic skin procedure subjects.
Methods: In this prospective, interventional, open-label, multicentric study, subjects who undergone post aesthetic procedures were enrolled to receive the application of SilverNova™ skin cream twice daily. The subjects received the topical application for seven days, after which they were followed up for the next seven days. Endpoints were assessed at baseline and the end of the treatment (EOT). Primary endpoints were the investigator-assessed erythema, edema, dryness/scaling score, and the subject-assessed product tolerability in terms of burning, stinging, itching, and dryness/tightness.
Results: A total of 60 subjects completed the study. There was a significant improvement in erythema, edema, and dryness/scaling score ($p<0.0001$). There was also significant improvement in burning, itching, and dryness/tightness scores. The physician global improvement assessment scale score was reduced from 3.3 to 1.38 ($p<0.0001$), showing the resolution of the symptom severity post-treatment with SilverNova™ skin cream. Colorimetric characterization showed significant improvement in values at the end of the study, reflecting the improvement in skin color and erythema reduction. No adverse events were reported during the study.
Conclusions: The application of SilverNova™ cream in the immediate post procedure period significantly reduced the downtime of the treatment and improved patient acceptance of the treatment. This indicates that SilverNova™ skin cream is a promising therapeutic option for managing the complications associated with aesthetic skin procedures without any safety concerns.

Keywords: AgNPs, SilverSol® technology, Chemical peeling, Laser hair removal, Soft-tissue fillers, Facial rejuvenation

INTRODUCTION

Facial rejuvenation procedures have become increasingly popular over traditional surgery. Minimally invasive procedures have increased over the past decades with a steady decline in conventional surgical procedures, including rhytidectomy and blepharoplasty.[1,2]

Highly effective and popular non-invasive rejuvenation procedures include injectable botulinum toxin (BoNT), soft-tissue fillers, and chemical peels. Non-invasive or minimally invasive procedures for improving facial aesthetics have the advantage of minimal downtime and a low risk of complications. These minimally invasive techniques provide quick and reliable skin rejuvenation with a low risk of complications and high patient satisfaction.[1,2]

These procedures are usually performed safely and effectively. However, complications can occur even with non-invasive aesthetic skin procedures despite their simplicity and reliability. More severe complications like muscle paralysis from BoNT, granuloma formation from soft-tissue filler placement, and scarring from chemical peels are fortunately rare and are avoidable with excellent procedure technique.[1]

Certain complications, including local reactions such as bleeding, pain, edema, erythema, and ecchymosis at the injection site, are common after the BoNT injection. Swelling, bruising, pain, and pruritus are the most commonly reported local injection site reactions with soft-tissue fillers. While prolonged erythema and pruritus, delayed wound healing, infection, textural changes to the skin, induction of acne or milia, and pigmentation changes such as post-inflammatory hyperpigmentation, are frequently reported adverse events with chemical peels. These side effects are usually transient, have simple remedies, and can be managed with appropriate pre- and post-skin care.[1,2]

Nanotechnology is one of the most trendsetting innovations in the twenty-first century. The advances in nanotechnology have enabled us to create new therapeutic horizons. It is also now increasingly becoming part of cosmeceuticals.[3,4] Silver nanoparticles (Ag-NPs), also called colloidal nanosilver, are an important addition to the area of nanomaterials. AgNPs are the most widely researched metallic nanoparticles because of the diversity it provides in terms of application. AgNPs are now well established in nanocosmeceuticals due to their broad spectrum of pharmacology applications.

The antimicrobial and anti-inflammatory properties of AgNPs are the main attraction in the development of nanocosmeceuticals. Researchers have taken advantage of utilizing these property of AgNPs by incorporating them as active ingredients in the preparation of the skincare products.[5]

Although the use of silver nanoparticles is rapidly increasing in cosmetics, there is limited research available on its use in managing complications of non-invasive or minimally invasive aesthetic skin procedures. This study evaluated the efficacy and safety of SilverNova™ skin cream composed of SilverSol® (patented colloidal nano silver technology from American Biotech Labs, USA), in combination with skin rejuvenators including coconut oil, vitamin E, and hyaluronic acid in post-aesthetic skin procedure subjects. SilverNova™ is registered trademark of Viridis BioPharma Pvt. Ltd., Mumbai.

METHODS

Study design and oversight

This was a prospective, interventional, open-label, multicentric study. The study was conducted at three hospital settings, Maven's hospital, Ajmer, Excel hospital, Secunderabad, and Jyoti Multispecialty Clinic, Pune. The study was conducted from 12th August 2022 to 20th October 2022. The study was approved by institutional ethics committee (Protocol number: ICBio/CR/VBPL/0517/003; Dated: 17/05/2022) and was registered in clinical trials registry- India (CTRI registration no: CTRI/2022/07/043752 Dated: 06/07/2022). The trial was conducted as per the Indian council of medical research (ICMR) guidelines (2017) for biomedical research on human subjects, international council on harmonization (ICH) guidelines for good clinical practice (E6R2), new drug and clinical trials rules 2019, declaration of Helsinki (Brazil, 2013) and in accordance with other applicable guidelines. All patients provided written consent to participate in the study before being screened. The investigator explained the details of the study procedure to each patient during the screening visit.

Participants

Male and female subjects between the age of 18 to 45 years were enrolled in the study. The subjects were eligible to enroll in the study if they have undergone aesthetic skin procedures, including chemical peeling (Tri chloroacetic acid (TCA) cross peel, yellow peel, black peel, glycolic peel, etc.), laser hair removal and micro-needling radio frequency for atrophic acne scars. The subjects were of general good health, had no obvious skin disease, and had a known history of atopic dermatitis and/or skin elastosis on the face. They agreed to refrain from using any new products other than the assigned test materials.

Subjects were excluded if they had any dermatological disorder that, in the investigator's opinion, may interfere with the accurate evaluation of the subject's face. Other key exclusion criteria were a previous hypersensitivity reaction to any of the ingredients of the study products and concurrent therapy with any medication that might

interfere with the study. Subjects who have used a topical retinoid or other cosmeceutical preparation within two weeks of study enrollment, including kojic acid, vitamin C, licorice extracts, alpha hydroxy acids, etc., were excluded from the study. Subjects were not included if were pregnant, breastfeeding, or planning a pregnancy.

Treatment

The study was planned with 60 subjects as per the approved protocol. Patients were instructed to apply a thin film of SilverNova™ skin cream to the affected areas of the skin twice daily. One fingertip unit (a line from the tip of an adult index finger to the first crease) was enough to cover an area twice the size of an adult hand. Patients were asked to follow the instructions of the investigator.

The total duration of the study was 14 days, with seven days of treatment and follow-up after seven days on the 14th day. Three visits were planned for the assessment of primary and secondary outcomes. At visit-1, baseline parameters were assessed. At the end of the treatment on day 7, visit-2 was planned to assess the changes in parameters from the baseline. Visit-3 was follow-up visit.

Primary and secondary endpoints

The primary endpoints evaluated were investigator-assessed parameters, including erythema, edema, and dryness/scaling on a 5-point ordinal scale (0=none, 1=minimal, 2=mild, 3=moderate, 4=severe), and subjects assessed parameters including burning, stinging, itching, dryness/tightness on a 5-point ordinal scale (0=none, 1=minimal, 2=mild, 3=moderate, 4=severe).

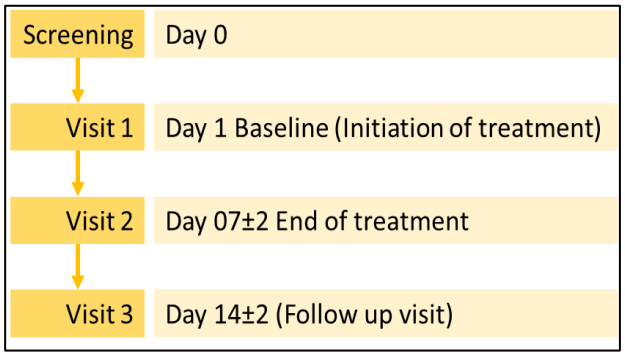

Figure 1: Study design.

Secondary endpoints included a percent reduction in a pigmentation by physician global improvement assessment scale from baseline to EOT and assessment of lightening of the skin using a chromameter. The outcomes of colorimetric characterization with chromameter were presented as L*a*b* values, where L* expresses the color's lightness on the black-white axis, a* expresses red/green intensity on the red-green axis, and b* gives the color position on the blue-yellow axis. Three images were taken of each subject's face (right, left, and center full face) at baseline and EOT to document visible changes in the skin.

Safety assessment

Clinical safety was assessed by evaluating the prevalence and incidence of adverse events (AEs) reported and/or observed during the study period.

Statistical analysis

Data analyzed with 5% significance level and 80% power for study using statistical software SAS® v 9.1.3. Difference within group was assessed using paired t test.

RESULTS

Demographics and other baseline characteristics

A total of 60 Patients were enrolled in the study, and 60 subjects completed the study. All the patients enrolled in the trial were compliant during treatment period. The demographic pattern of participant is given in Table 1.

Table 1: Demographic data of the study participants.

Characteristics	N
Total participants	60
Male	25
Female	35
Mean age (in Years)	28.65
Mean weight (in Kg)	66.38
Mean height (in cm)	159.98
Mean BMI (kg/m^2)	25.84

Primary endpoints

Investigator evaluated erythema, edema, and dryness/ scaling

There was an improvement in the erythema score from baseline to EOT. There was also an improvement in edema and dryness/scaling scores at EOT.

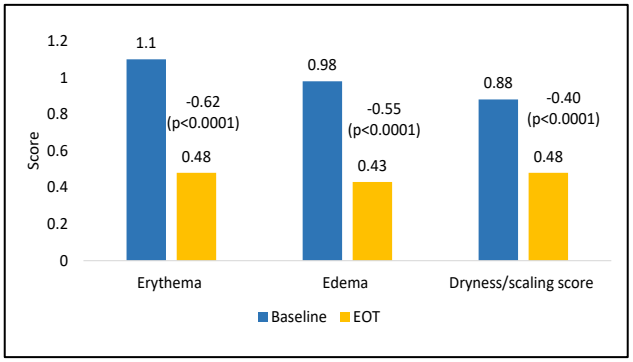

Figure 2: Changes in investigator evaluated erythema, edema, and dryness/ scaling scores from baseline to EOT.

Change from baseline to EOT was statistically significant in all 3 parameters (Figure 2). Erythema score reduced from 1.1 at baseline to 0.48 at EOT (-0.62; p<0.0001), the edema score reduced from 0.98 at baseline to 0.43 at EOT (-0.55; p<0.0001) and dryness/scaling score reduced from 0.88 at baseline to 0.48 at EOT (0.40; p<0.0001).

Subjects assessed burning, stinging, itching, dryness/tightness

There was a statistically significant improvement in subjects assessed burning, itching, and dryness/tightness scores (Figure 3).

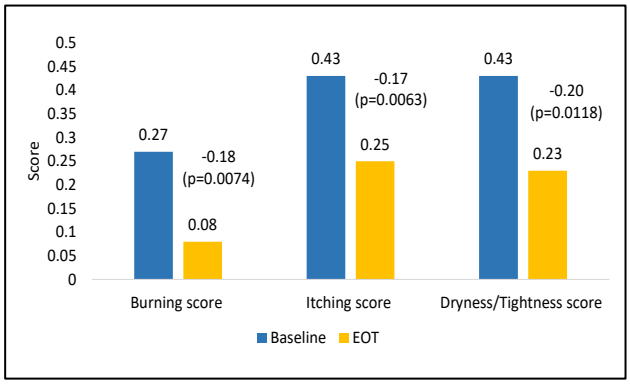

Figure 3: Changes in subjects assessed burning, stinging, itching, dryness/tightness scores from baseline to EOT.

Burning score reduced from 0.27 at baseline to 0.08 at EOT (-0.18; p=0.0074), itching score reduced from 0.43 at baseline to 0.25 at EOT (-0.17; p=0.0063) and dryness/ tightness score reduced from 0.43 at baseline to 0.23 at EOT (-0.20; p=0.0118). There was also improvement in stinging from baseline to EOT (Data not shown).

Secondary endpoints

Physician global improvement assessment

A statistically significant difference was observed from baseline to EOT for physician global improvement assessment scale score (p<0.0001; Figure 4).

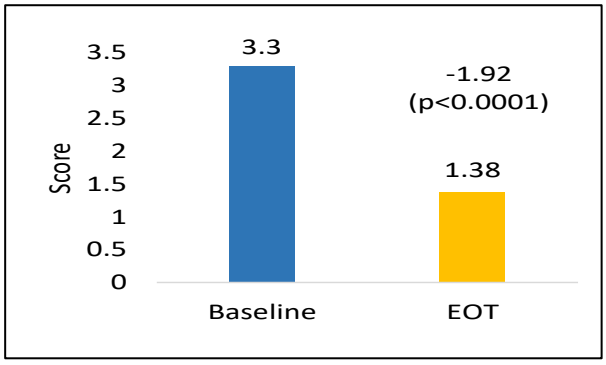

Figure 4: Physician global improvement assessment.

The physician global improvement assessment scale score changed by 70.83% from baseline to EOT.

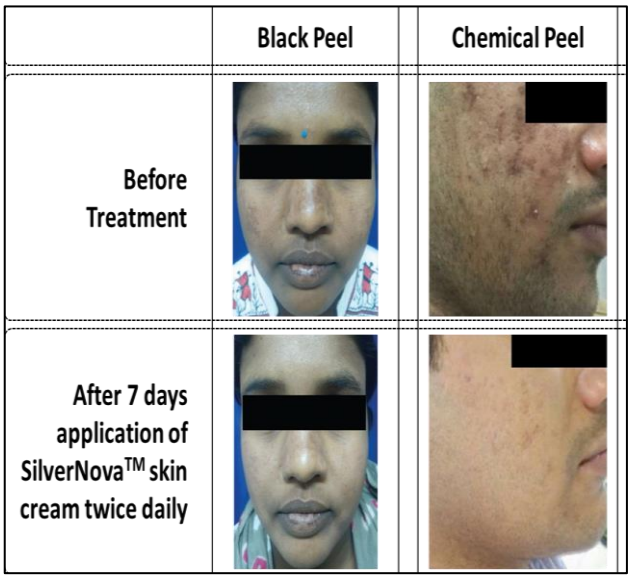

Figure 5: Representative photographic images.

Visible changes in the skin were also documented at the end of the study (Figure 5).

Lightening of the skin assessment

Lightening of the skin assessment using chromameter measurements showed a statistically significant difference observed from baseline to EOT for L*, a*, and b* values (Figure 6).

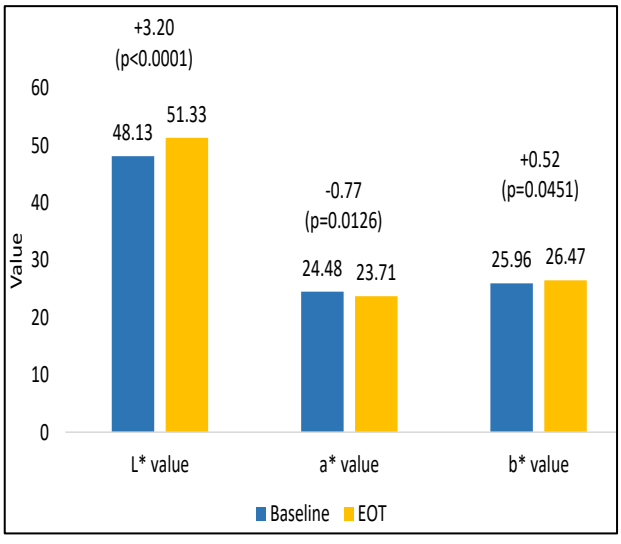

Figure 6: Lightening of the skin assessment using chromameter measurements.

The L* value improved from 48.13 at baseline to 51.33 at EOT (+3.20; p<0.0001); a* value improved from 24.48 to 23.71 (-0.77; p=0.0126), and the b* value improved from 25.96 to 26.47 (+0.52; p=0.0451).

Safety

There were no adverse events or adverse drug reactions observed among all subjects. This confirmed that the test product was found safe to be used in humans.

DISCUSSION

AgNPs, also called as colloidal nanosilver, are a valuable addition to cosmeceuticals owing to their advantageous therapeutic attributes. Newer and diverse cosmetic formulations with the use of AgNPs have emerged in the cosmeceutical market for the prevention or treatment of prevalent dermatological conditions, to heal damaged skin and subsequently preserve overall skin health and quality for long-term.[5]

AgNPs have potent antimicrobial properties and impressive anti-inflammatory properties.[6] Studies have also demonstrated the wound-healing properties of AgNPs. In a recently conducted study, it has been shown that SilverSol® can exert potent activity against different species of parasitic helminths.[7] The SilverSol® gel was effective in preventing biofilm formation by *S. mutans*, *S. sanguis*, and *S. salivarius*.[8] In an in vitro study, the SilverSol® gel in combination with Betadine antiseptic solution was proven to be effective in inhibiting the growth of bacterial biofilms.[9] In a clinical study[10], the SilverSol® gel was shown to be effective in several oro-dental conditions including periodontitis and gingivitis.

It has been shown that AgNPs disrupt the vascular endothelial growth factor (VEGF) pathway, which is responsible for the T-helper type-2 (TH2) cell-mediated inflammation promoted by secretion of pro-inflammatory cytokines like IL-4, IL-5, IL-9, and IL-13.[11] Preclinical studies have reported that AgNPs alter the inflammatory response via various mechanisms. AgNPs lower inflammation and regulate the release of fibrogenic cytokines, thus promoting rapid healing. It has also been observed that AgNPs decrease inflammation markers such as tumor necrosis factor-alpha (TNF-a) and interleukin (IL)-6 in animal models.[5] Jurairattanaporn et al. compared AgNPs gel with 1% clindamycin gel when combined with 2.5% benzoyl peroxide in patients with moderate acne vulgaris. There was a significant improvement in inflammatory and non-inflammatory acne scores with AgNPs gel. There was also an improvement in clinical erythema score and Mexameter erythema index with AgNPs gel. AgNPs also demonstrated a good safety profile in this study.[12] A study by Crisan and coworkers evaluated the impact of AgNPs on psoriatic inflammation. In their study, the incubation of pro-inflammatory macrophages with AgNPs significantly decreased the release of NO, IL-12, and TNF-α. AgNPs also repressed NF-κB activation in macrophages, inhibiting the production of pro-inflammatory factors. AgNPs treatment also resulted in significant subjective and clinical improvement of psoriasis plaques, with reduced scaling and erythema.[13]

There are multiple studies demonstrating the wound-healing mechanisms of AgNPs. It is proposed that the topical application of AgNPs can promote wound healing through the modulation of cytokines. AgNPs also assist the proliferation and migration of keratinocytes and reduce the formation of collagen by fibroblasts.[14,15]

Kuruwa et al conducted a pilot study to assess the safety and efficacy of a colloidal nanosilver skin cream that contained SilverSol®, a patented colloidal nanosilver, along with coconut oil, vitamin E, and hyaluronic acid, as active ingredients. The study included patients who had experienced adverse side effects, such as erythema, itching, burning sensations, skin scarring, and erosion, following aesthetic skin procedures. After applying the colloidal nanosilver skin cream to the affected area for seven days, a reduction in redness and pigmented scars were observed in these patients. Notably, no sensations of burning or itching were reported.[16]

Current literature is suggestive of the potential use of AgNPs in the treatment of complications of minimally invasive aesthetic procedures. Our study was planned to assess the effectiveness, safety, and tolerability of SilverNova™ skin cream composed of silver nanoparticles in post-aesthetic skin procedure subjects.

Bruising, pain, edema, erythema, irritation, burning, and dry skin are the most common complications of aesthetic skin procedures due to inflammation.[1,2] AgNPs which are potential anti-inflammatory agent have a large surface area to volume ratio and do better at blocking inflammation-enhancers like cytokines and inflammation-assisting enzymes than their larger sized complements.[7] In our study, treatment with SilverNova™ skin cream for seven days significantly improved investigator as well as subject-assessed primary efficacy parameters, including erythema, edema, burning, stinging, itching, dryness/scaling, and tightness.

Physician's global assessment (PGA) scale is the scoring system used to evaluate the disease severity. PGA is also a reliable tool to assess and track treatment outcomes. PGA scoring also provides a quantifiable metric to demonstrate the efficacy of dermatologic care and allows the evaluation of the degree of clinical improvement.[17] In the current study, the PGA scale score improved significantly at EOT, which shows that the severity of the symptoms reduced significantly with the treatment of SilerNova™ skin cream.

Chromameter (Tristumulus colorimeter) characterizes skin color and quantifies small skin color changes under color organization systems, such as the CIELAB color space, standardized by the commission internationale de l'Eclairage (CIE). The L*a*b* values can be transcribed to dermatological parameters where the L* value correlates with the level of pigmentation of the skin, a* value correlates with erythema, and b* value correlates with pigmentation and tanning.[18] Skin colour is an

admixture of the L*a*b* values. Increment in erythema or tanning darkens the skin and decreases the L* value and b* value and increase the a* value. Hence, there is an increase in the L* and b* values and decrease in the a* value when there is decrease in erythema or lightning of tanned skin.[19] In the current study, the mean L* and b* values were significantly ($p<0.0001$ and $p=0.0451$, respectively) increased at EOT, showing significant skin lightening, while the mean a* value was significantly decreased at EOT, depicting the significant reduction in erythema, which also reflects the significant reduction in erythema score in the primary analysis.

The safety of AgNPs with the topical application and human consumption has been demonstrated in previous studies.[20,21,22] Increased surface-to-volume ratio in AgNPs makes silver more potent at reduced concentrations which further lowers the toxicity of silver particles depending on the size and shape of the nanoparticles.[23] George et.al. evaluated the dermal and systemic absorption of AgNPs through healthy human skin. The results of the study showed that AgNPs are able to penetrate intact human skin in vivo beyond the stratum corneum as deep as the reticular dermis. However, the AgNPs did not reach systemic circulation and thus are safe for topical application.[24] Our study results showed that the silver nanoparticles are safe to use in the treatment of complications post aesthetic skin procedures without any noticeable adverse effects.

Apart from colloidal nanosilver, SilverNova™ skin cream also contains skin rejuvenators, including coconut oil, vitamin E, and hyaluronic acid. These skin rejuvenators add to the benefits of colloidal nanosilver. Coconut oil heals skin, reduces inflammation, and improves protective barrier functions,[25] vitamin E increases ceramides, and has anti-inflammatory and photoprotective effects,[26] while, hyaluronic acid moisturizes, helps tissue regeneration, and preserves the structural integrity of the skin. [27]

Taken together, the use of SilverNova™ skin cream in post-aesthetic procedure subjects provides a novel therapeutic direction for the management of complications associated with minimally invasive aesthetic procedures in routine clinical practices.

Limitations

The study is conducted as an open labelled study with a small sample size for each procedure. Further studies need to be conducted as double-blind placebo controlled with larger sample size population.

CONCLUSION

The silver nanoparticle had significant therapeutic efficacy in managing the complications associated with aesthetic skin procedures in this study. The benefits of the SilverNova™ skin cream may also be due to the presence of other skin rejuvenators. The outcomes of this study indicate that SilverNova™ skin cream is a promising therapeutic option for managing the complications associated with aesthetic skin procedures without any safety concerns. The application of SilverNova cream in the immediate post procedure period significantly reduced the downtime of the treatment and improved patient acceptance of the treatment. The cream was found to be effective and safe in the treatment of complications associated with aesthetic skin procedures. It is proposed that SilverNova™ skin cream can be used in post-aesthetic skin care to treat redness, swelling, burning sensation, scarring, hyperpigmentation, bruising, dryness, flaking of the skin, and infections.

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Conflict of interest: One of the authors, Anirudh Mehta is from Viridis BioPharma Pvt. Ltd., who manufacture and market SilverSol®. However, this has not affected the design of the study or interpretation of data anyway. The rest of the authors have no competing interests to declare
Ethical approval: The study was approved by the Independent Ethics Committee for Jyoti Multispecialty Clinic and Institutional Ethics Committees for Maven's Hospital and Excel Hospital. This study was registered in Clinical Trials Registry- India (CTRI/2022/07/043752 Dated: 06/07/2022).

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