ORIGINAL RESEARCH ARTICLE

Efficacy of recombinant human collagen serum for improving skin dryness and roughness in striae gravidarum: a clinical study

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Abstract

Striae gravidarum is common after pregnancy and may be accompanied by skin dryness, roughness, and visible textural irregularity that affect quality of life. This prospective, self-controlled clinical study evaluated whether a topical recombinant human collagen serum could improve the biophysical characteristics of postpartum striae gravidarum. Twenty postpartum women with bilateral abdominal striae applied the serum twice daily to one randomly assigned abdominal side for 4 weeks, while the contralateral side served as the within-participant control. Skin elasticity, firmness, striae area, and surface roughness were assessed at baseline, week 2, and week 4 using standardized non-invasive instruments and digital image analysis. Longitudinal modeling showed greater improvement on the treated side than on the control side, particularly for elasticity, visible striae area, and surface roughness. Multivariate analysis indicated that reductions in striae area and roughness occurred in a coordinated pattern, suggesting overall structural improvement of the affected skin. The serum was well tolerated, with only mild transient erythema in two participants. These findings indicate that recombinant human collagen serum is a promising non-invasive option for improving postpartum striae gravidarum-related dryness, roughness, and skin texture. *(Afr J Reprod Health 2026; 30 [13]: 86-100).*

Keywords: Striae gravidarum; recombinant human collagen; skin dryness; skin roughness; postpartum skin

Résumé

Les vergetures gravidiques sont fréquentes après la grossesse et peuvent s'accompagner de sécheresse cutanée, de rugosité et d'irrégularités visibles de la texture de la peau, affectant ainsi la qualité de vie. Cette étude clinique prospective et auto-contrôlée a évalué si un sérum topique à base de collagène humain recombinant pouvait améliorer les caractéristiques biophysiques des vergetures gravidiques postpartum. Vingt femmes en période postpartum présentant des vergetures abdominales bilatérales ont appliqué le sérum deux fois par jour sur un côté abdominal attribué aléatoirement pendant 4 semaines, tandis que le côté controlatéral servait de contrôle intra-individuel. L'élasticité et la fermeté de la peau, la surface des vergetures et la rugosité cutanée ont été évaluées au départ, à la deuxième semaine et à la quatrième semaine à l'aide d'instruments standardisés non invasifs et d'une analyse numérique des images. Les modèles longitudinaux ont montré une amélioration plus importante du côté traité par rapport au côté témoin, en particulier pour l'élasticité, la surface visible des vergetures et la rugosité de surface. L'analyse multivariée a indiqué que les réductions de la surface des vergetures et de la rugosité se produisaient de manière coordonnée, suggérant une amélioration structurelle globale de la peau affectée. Le sérum a été bien toléré, avec seulement un érythème transitoire léger chez deux participantes. Ces résultats indiquent que le sérum de collagène humain recombinant constitue une option non invasive prometteuse pour améliorer la sécheresse, la rugosité et la texture cutanée associées aux vergetures gravidiques postpartum. *(Afr J Reprod Health 2026; 30 [13]: 86-100).*

Mots-clés: Vergetures gravidiques ; collagène humain recombinant ; sécheresse cutanée ; rugosité cutanée ; peau postpartum

Introduction

Striae gravidarum, commonly referred to as stretch marks, represents one of the most prevalent dermatological manifestations during pregnancy, affecting between 55% and 90% of pregnant women globally.[1,2] These characteristic linear bands initially present as erythematous or

violaceous marks and progressively evolve into hypopigmented, atrophic scars.[3] Although medically benign, striae gravidarum can cause substantial psychological distress, negatively impacting self-esteem and quality of life, particularly in postpartum women.[4,5]

The pathophysiology of striae gravidarum involves a complex interplay of mechanical stretching and hormonal factors during pregnancy. Rapid skin distension coupled with elevated levels of estrogen, relaxin, and adrenocortical hormones leads to decreased collagen fiber adhesiveness and increased ground substance, ultimately resulting in dermal structural disruption.[6,7] Histologically, striae gravidarum demonstrate elastolysis in the mid-dermis, perivascular lymphocytic infiltration, and realignment of collagen fibers into parallel arrays with reduced elastic fiber density.[8] These structural alterations manifest clinically as loss of skin elasticity, increased surface roughness, and visible textural changes.

Multiple risk factors have been associated with the development and severity of striae gravidarum. Younger maternal age, family history, excessive gestational weight gain, higher pre-pregnancy body mass index, and increased neonatal birth weight independently correlate with striae occurrence.[9,10] The condition predominantly affects the abdomen, breasts, and thighs, corresponding to areas experiencing maximal mechanical stress during pregnancy.[11] Despite extensive research, effective preventive and therapeutic strategies remain limited, highlighting an urgent need for evidence-based interventions.

Collagen, comprising approximately 75% of skin dry weight, serves as the principal structural protein maintaining dermal integrity and mechanical properties.[12] Type I and type III collagens form the predominant components of the dermal extracellular matrix, providing tensile strength and elastic recoil. The degradation and disorganization of these collagen networks constitute a fundamental mechanism underlying striae formation.[13] Consequently, therapeutic approaches targeting collagen restoration have garnered significant attention in striae gravidarum management.

Recombinant human collagen, produced through advanced recombinant DNA technology, represents a biomaterial that addresses critical limitations of animal-derived collagens, including immunogenicity concerns and zoonotic disease transmission risks.[14] Recent clinical investigations have demonstrated that recombinant human collagen exhibits favorable mechanical properties, controlled degradation rates, and good biocompatibility compared with traditional collagen sources.[15] In vitro studies have shown that recombinant human collagen can promote fibroblast proliferation, stimulate endogenous collagen synthesis through receptor-mediated signaling pathways, and facilitate extracellular matrix remodeling.[15] These biological activities position recombinant human collagen as a promising candidate for topical treatment of striae gravidarum.

To objectively assess the efficacy of topical interventions for striae gravidarum, validated biophysical measurement techniques are essential. The Cutometer, which uses negative pressure to deform skin and measure viscoelastic properties, provides reliable quantification of elasticity parameters such as gross elasticity and biological elasticity.[16] These non-invasive instruments have demonstrated good reliability and reproducibility in assessing skin mechanical properties across anatomical sites.[17] Surface topography analysis enables precise quantification of striae area and roughness, offering objective metrics for treatment response evaluation.[18]

Traditional statistical approaches for analyzing repeated measures data, such as paired t-tests or repeated measures analysis of variance, often fail to adequately account for within-subject correlation, missing data patterns, and individual variability in treatment response. Linear mixed-effects models provide a sophisticated analytical framework that addresses these limitations by incorporating both fixed effects and random effects, thereby yielding more accurate and robust inference.[19] This modeling approach has gained widespread adoption in medical research for its ability to handle complex longitudinal data structures.[20]

Furthermore, striae gravidarum treatment efficacy should ideally be evaluated using multivariate outcome measures rather than isolated parameters, as skin improvement likely involves

coordinated changes across multiple biophysical domains. Principal component analysis offers a dimension-reduction technique to identify underlying patterns of covariation among multiple outcome measures, facilitating a comprehensive understanding of treatment mechanisms.[21] By extracting principal components that capture maximal variance in multivariate data, this approach enables researchers to characterize holistic improvement profiles and identify subgroups with differential treatment responses.[22]

Despite the theoretical promise of recombinant human collagen for striae gravidarum treatment, rigorous clinical evidence employing advanced analytical methodologies remains scarce. Most existing studies rely on subjective assessments or univariate analyses of single outcome measures, limiting their scientific rigor and clinical applicability. To address this knowledge gap, we conducted a prospective, self-controlled clinical study to evaluate the efficacy of topically applied recombinant human collagen serum in improving multiple biophysical parameters of striae gravidarum-affected skin. Our study employed linear mixed-effects modeling to rigorously quantify time × treatment interaction effects while adjusting for potential confounders, and utilized principal component analysis to elucidate multivariate improvement patterns.

Methods

Study design and participants

This prospective, self-controlled clinical study was conducted from April to June 2025 in the Department of Obstetrics, The First Hospital of Tsinghua University (Beijing Huaxin Hospital), Beijing, China.

Eligible participants were postpartum women aged 25-45 years with visible striae gravidarum on the abdomen, confirmed by clinical examination. (1) Inclusion criteria comprised: postpartum period of 6-24 months, presence of bilateral symmetric striae gravidarum suitable for split-body comparison, stable body weight (±2 kg) for at least 3 months prior to enrollment, and willingness to adhere to study protocol and attend all scheduled visits. (2) Exclusion criteria included: active skin infections or inflammatory conditions in the treatment area, history of keloid formation or hypertrophic scarring, concurrent use of other topical treatments for striae gravidarum within 4 weeks of enrollment, systemic corticosteroid use within 3 months, diagnosed connective tissue disorders (Marfan syndrome, Ehlers-Danlos syndrome), pregnancy or lactation at enrollment, and known hypersensitivity to collagen-based products.

Sample size calculation was based on pilot data indicating a mean difference in R2 elasticity of 0.04 units between test and control sides with a standard deviation of 0.05. To detect this difference with 80% power at a two-sided significance level of 0.05, accounting for within-subject correlation (ρ=0.5) and potential 10% dropout, a minimum of 18 participants was required. We enrolled 20 participants to ensure adequate statistical power.

Intervention

The investigational product was Shinestyle Professional Firming & Anti-wrinkle Essence (Beijing Haomiao Riyue Biotechnology Co., Ltd.). The serum formulation also contained hyaluronic acid (0.1%), glycerin (5%), and preservatives in a pH-balanced aqueous base. Recombinant human collagen was selected for its structural similarity to endogenous human collagen, hypothesized biocompatibility, and absence of animal-derived components.

Participants were instructed to apply 2 mL of the collagen serum to the designated test side (randomly assigned to either left or right abdominal side) twice daily (morning and evening) for 28 consecutive days. The contralateral side received no active treatment and served as within-subject control. To standardize application technique, participants received detailed instructions during the baseline visit, including demonstration of gentle circular massage for 2-3 minutes until complete absorption. Participants maintained a diary documenting application compliance and any adverse events.

Outcome measures

All measurements were performed by trained assessors blinded to treatment allocation at three time points: baseline (BL, Day 0), week 2

(W2, Day 14±2), and week 4 (W4, Day 28±2). Measurements were conducted in a temperature-controlled room (22±1°C, 50±5% relative humidity) following a 30-minute acclimatization period. Participants were instructed to avoid application of any topical products for at least 12 hours prior to assessment visits.

Skin elasticity (R2 Parameter)

Skin elasticity was measured using the Cutometer® dual MPA 580 (Courage+Khazaka Electronic GmbH, Cologne, Germany) with a 2-mm probe. The device applies controlled negative pressure (450 mbar for 2 seconds) to deform the skin, followed by a 2-second relaxation phase. The R2 parameter (Ua/Uf ratio), representing gross elasticity or the ability of skin to return to its original position, was calculated as the ratio of immediate retraction to total deformation. Higher R2 values indicate better elastic recovery. Three measurements were performed at standardized locations within the striae-affected area on each side, and the mean value was recorded for analysis.

Skin firmness (F4 Parameter)

Skin firmness was assessed using the Cutometer F4 parameter derived from the deformation curve during the suction phase. F4 reflects biological elasticity and is calculated from the slope of the final portion of the retraction curve. Lower F4 values indicate firmer skin with greater resistance to deformation. Measurements were obtained concurrently with R2 assessments using identical protocols.

Striae gravidarum area

Striae area was quantified using standardized digital photography combined with image analysis software. High-resolution images (24 megapixels) were captured under standardized lighting conditions using a calibrated medical photography system (Canfield VISIA® Complexion Analysis System, Canfield Scientific Inc., Parsippany, NJ). A standardized measurement template (10×10 cm) was placed over the most affected area on each side. Images were analyzed using ImageJ software (version 1.53, National Institutes of Health, USA) by a blinded assessor who manually delineated striae boundaries. The total striae area (mm^2) within the template was calculated and expressed as a percentage of the total measurement area.

Surface roughness (Ra Parameter)

Surface roughness was evaluated using the Visioscan® VC 98 (Courage+Khazaka Electronic GmbH, Cologne, Germany), a non-invasive optical device utilizing video microscopy and image analysis. The system captures high-resolution images of skin surface topography within a 6×8 mm field. The Ra parameter (arithmetic mean roughness) quantifies the average deviation of the surface profile from the mean line, with higher values indicating increased roughness. Three measurements per side were obtained and averaged.

Additional data collection

Demographic information including age, height, weight, parity, time since last delivery, and gestational weight gain were collected at baseline. Body mass index (BMI) was calculated as weight (kg) divided by height squared (m^2). Adverse events were systematically recorded at each visit using structured questionnaires assessing local skin reactions (erythema, pruritus, burning sensation) and systemic symptoms.

Statistical analysis

All statistical analyses were performed using Python 3.9 with the statsmodels, pandas, and scikit-learn libraries. Statistical significance was set at $\alpha=0.05$ (two-sided). Continuous variables are presented as mean ± standard deviation, and categorical variables as frequencies and percentages. Baseline comparability between test and control sides was assessed using paired t-tests, with normality evaluated by the Shapiro-Wilk test. Linear mixed-effects models were separately fitted for each outcome variable (R2, F4, striae area, and Ra), including fixed effects for time, side, and their interaction, with age and BMI as centered covariates and participant as a random intercept. The primary endpoint was the Time[W4] × Side[Test] interaction coefficient, representing the differential treatment effect at week 4. Models were

estimated using restricted maximum likelihood (REML), and assumptions were assessed through residual diagnostics. Change scores from baseline to week 4 on the treated side (ΔR2, ΔF4, ΔArea, and ΔRa) were calculated for correlation analysis using Pearson coefficients. Principal component analysis (PCA) was performed on standardized change scores to identify dominant patterns of covariation. Components with eigenvalues >1.0 were retained, and component loadings were examined for interpretation. Correlations between principal component scores and baseline demographic variables were explored using Pearson correlation analysis.

Ethical considerations

The study protocol received approval from the Ethics Committee for Biomedical Research Involving Human Subjects of Beijing Huaxin Hospital, Beijing, China (approval reference number: 2025-012-02(R); approval date: April 21, 2025; approval validity period: April 21, 2025 to April 20, 2026), and was conducted in accordance with the Declaration of Helsinki, Good Clinical Practice principles, and applicable regulatory requirements. All participants provided written informed consent before enrollment, and the study procedures were carried out in a manner that protected participant rights, safety, and privacy.

Results

Participant characteristics

A total of 20 postpartum women were enrolled, and all participants completed the 4-week study period. Complete measurements at all three time points were available for 18 participants, while two participants missed only the week 2 assessment because of scheduling conflicts and completed the baseline and week 4 visits. No participant withdrew. The baseline profile is summarized in Table 1. Participants were predominantly in their mid-thirties, with a mean body mass index in the normal to slightly overweight range, a median postpartum interval close to 1 year, and gestational weight gain values consistent with a typical postpartum population.

Baseline comparability between test and control sides

Baseline comparability analysis demonstrated no statistically significant differences between the treated and control sides for any biophysical parameter (Table 2). The mean baseline elasticity values were 0.805 on the treated side and 0.795 on the control side, and the baseline distributions of firmness, striae area, and roughness were also comparable. These findings support the internal validity of the split-body design.

Linear mixed-effects model results
Complete model estimates

Linear mixed-effects models were fitted for each outcome variable, incorporating fixed effects for time, side, their interaction, and centered covariates for age and body mass index, along with random intercepts for participants. Complete fixed-effect estimates are provided in Table 3. The models showed that the main treatment information was carried by the week 4 time-by-side interaction, which quantified the additional change on the treated side relative to the control side.

Primary efficacy outcomes

The week 4 time-by-side interaction coefficients are shown separately in Table 4 as the primary efficacy estimates. Compared with the control side, the treated side showed a statistically significant increase in elasticity (estimate 0.0415, 95% confidence interval 0.0142 to 0.0688, P=0.003), a significant reduction in striae area (estimate -46.6506, 95% confidence interval -72.1720 to -21.1291, P<0.001), and a significant reduction in surface roughness (estimate -0.6217, 95% confidence interval -1.1561 to -0.0872, P=0.023). Firmness showed a favorable but non-significant trend.

Temporal patterns

The temporal evolution of treatment effects is shown in Figures 1 and 2. Elasticity showed modest separation between sides at week 2 and a clearer difference by week 4, suggesting a cumulative

Table 1: Baseline demographic and clinical characteristics (N=20)

Characteristic	N	Mean ± SD	Range (Min-Max)	Percentile (25th-75th)
Age (years)	20	34.70 ± 4.12	30.00 - 43.00	31.75 - 36.25
Height (m)	20	1.63 ± 0.04	1.56 - 1.73	1.59 - 1.65
Weight (kg)	20	63.65 ± 7.91	50.00 - 80.00	58.00 - 70.00
BMI (kg/m²)	20	23.96 ± 2.88	18.82 - 31.25	22.44 - 25.78
Time since delivery (months)	20	11.3 ± 4.7	6.0 - 22.0	8.0 - 14.5
Parity	20	1.65 ± 0.75	1 – 3	1 - 2
Gestational weight gain (kg)	20	16.8 ± 4.2	9.0 - 24.0	14.0 - 19.5

Table 2: Baseline biophysical parameters by treatment side (N=18 with complete baseline data)

Parameter	Control SideMean ± SD	Test SideMean ± SD	Paired DifferenceMean (95% CI)	P-value
R2 (Elasticity)	0.795 ± 0.061	0.805 ± 0.043	-0.010 (-0.035, 0.015)	0.412
F4 (Firmness)	20.165 ± 3.149	20.059 ± 2.647	0.106 (-1.421, 1.633)	0.886
Striae Area (mm²)	103.216 ± 60.755	107.369 ± 49.295	-4.153 (-29.876, 21.570)	0.738
Ra (Roughness)	6.071 ± 1.037	6.158 ± 0.927	-0.087 (-0.478, 0.304)	0.643

Table 3: Fixed effects estimates from linear mixed-effects models

Parameter		Outcome	Estimate	SE	95% CI Lower	95% CI Upper	P-value
Intercept		R2	0.7951	0.0096	0.7763	0.8140	<0.001
Time[W2]		R2	0.0126	0.0099	-0.0067	0.0319	0.200
Time[W4]		R2	0.0070	0.0099	-0.0123	0.0263	0.478
Side[Test]		R2	0.0095	0.0099	-0.0098	0.0288	0.335
Time[W2] Side[Test]	×	R2	0.0070	0.0139	-0.0204	0.0343	0.617
Time[W4] Side[Test]	**×**	**R2**	**0.0415**	**0.0139**	**0.0142**	**0.0688**	**0.003**
Age (centered)		R2	-0.0010	0.0018	-0.0045	0.0026	0.589
BMI (centered)		R2	0.0027	0.0025	-0.0021	0.0076	0.271
Intercept		F4	20.165	0.603	18.983	21.346	<0.001
Time[W2]		F4	0.389	0.745	-1.072	1.849	0.602
Time[W4]		F4	-0.197	0.745	-1.657	1.263	0.792
Side[Test]		F4	-0.106	0.745	-1.566	1.354	0.887
Time[W2] Side[Test]	×	F4	-1.141	1.054	-3.206	0.924	0.279
Time[W4] Side[Test]	×	F4	-1.041	1.054	-3.106	1.025	0.323
Age (centered)		F4	-0.054	0.091	-0.231	0.124	0.553
BMI (centered)		F4	0.077	0.125	-0.168	0.321	0.539
Intercept		Area	103.216	10.550	82.539	123.892	<0.001
Time[W2]		Area	3.953	9.208	-14.093	22.000	0.668
Time[W4]		Area	6.083	9.208	-11.963	24.130	0.509
Side[Test]		Area	4.154	9.208	-13.893	22.200	0.652
Time[W2] Side[Test]	×	Area	-22.353	13.021	-47.875	3.168	0.086
Time[W4] Side[Test]	**×**	**Area**	**-46.651**	**13.021**	**-72.172**	**-21.129**	**<0.001**
Age (centered)		Area	-6.942	2.174	-11.203	-2.681	0.001

BMI (centered)		Area	-2.519	2.995	-8.388	3.351	0.400
Intercept		Ra	6.071	0.196	5.687	6.454	<0.001
Time[W2]		Ra	-0.021	0.193	-0.399	0.357	0.915
Time[W4]		Ra	-0.137	0.193	-0.515	0.241	0.477
Side[Test]		Ra	0.087	0.193	-0.291	0.465	0.651
Time[W2] Side[Test]	×	Ra	-0.478	0.273	-1.012	0.057	0.080
Time[W4] Side[Test]	**×**	**Ra**	**-0.622**	**0.273**	**-1.156**	**-0.087**	**0.023**
Age (centered)		Ra	-0.063	0.038	-0.137	0.010	0.092
BMI (centered)		Ra	-0.006	0.052	-0.108	0.096	0.906

Note: Bold rows indicate primary outcomes (Time[W4] × Side[Test] interaction effects). Reference levels: Time=BL, Side=Control. SE = Standard Error; CI = Confidence Interval.

Table 4: Primary treatment effects at week 4 (Time × side interaction coefficients)

Outcome Parameter	Estimate	SE	95% CI Lower	95% CI Upper	P-value	Effect Size
R2 (Elasticity)	0.0415	0.0139	0.0142	0.0688	0.003	+5.2% improvement
F4 (Firmness)	-1.0406	1.0537	-3.1058	1.0247	0.323	-5.2% trend
Striae Area	-46.6506	13.0214	-72.1720	-21.1291	<0.001	-43.2% reduction
Ra (Roughness)	-0.6217	0.2727	-1.1561	-0.0872	0.023	-10.1% reduction

Note: Effect sizes calculated as (Week 4 estimate / baseline control mean) × 100%. Negative estimates indicate favorable outcomes for Area and Ra.

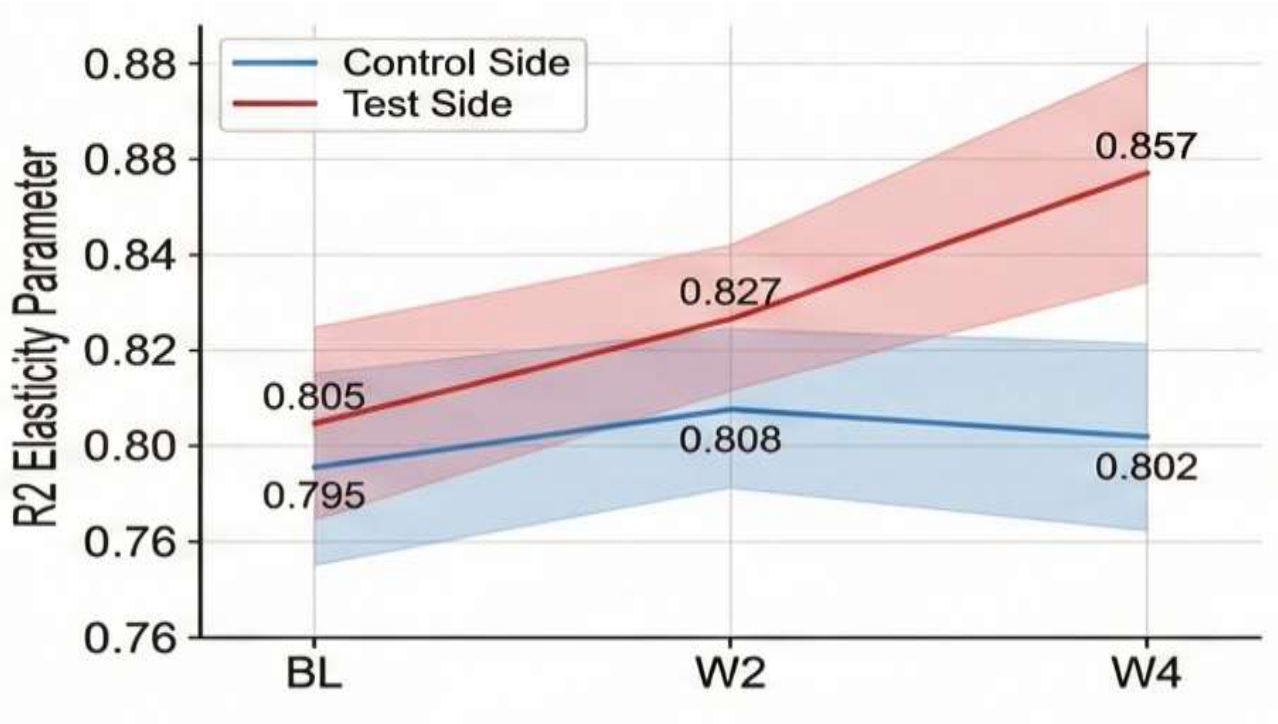

Figure 1: Predicted trajectories of R2 elasticity parameter from mixed-effects model for control side (blue line) and test side (red line). Shaded regions represent 95% confidence intervals. Time points: BL = baseline, W2 = week 2, W4 = week 4

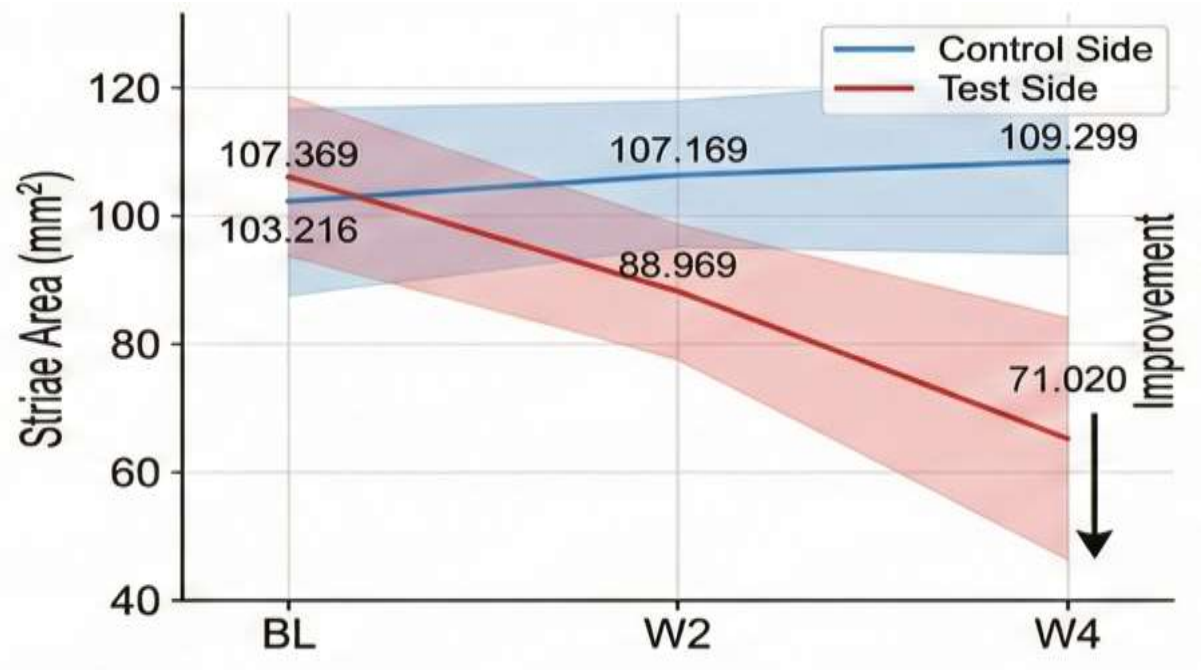

Figure 2: Predicted trajectories of striae area from mixed-effects model for control side (blue line) and test side (red line). Shaded regions represent 95% confidence intervals. Time points: BL = baseline, W2 = week 2, W4 = week 4.

improvement over the treatment period. Striae area decreased earlier, with visible divergence by week 2 and further reduction by week 4, indicating that morphological changes in the treated region were detectable within the first half of the study.

Forest plot of interaction effects

To facilitate cross-parameter comparison, the primary week 4 interaction coefficients and their 95% confidence intervals are displayed in Figure 3. The confidence intervals for elasticity, striae area, and roughness did not cross the null value, whereas the interval for firmness included zero. This pattern indicates that the most consistent treatment-associated effects were observed in elasticity recovery, visible striae reduction, and surface smoothing.

Multivariate correlation analysis

Correlation analysis of week 4 change scores on the treated side revealed distinct patterns of association among the biophysical outcomes (Table 5 and Figure 4). The strongest association was observed between reduction in striae area and reduction in roughness (r=0.671), indicating that improvement in visible lesion extent occurred in parallel with improvement in surface texture.

Principal component analysis

Principal component analysis of the four standardized change scores yielded two components with eigenvalues greater than 1.0, together explaining 71.8% of the total variance (Table 6 and Figure 5). The first component was dominated by striae area and roughness, consistent with a structural improvement domain, whereas the second component was dominated by elasticity and firmness, consistent with a biomechanical improvement domain.

Relationship between composite improvement and baseline characteristics

To explore potential predictors of treatment response, the first principal component score, representing composite structural improvement, was correlated with baseline demographic and

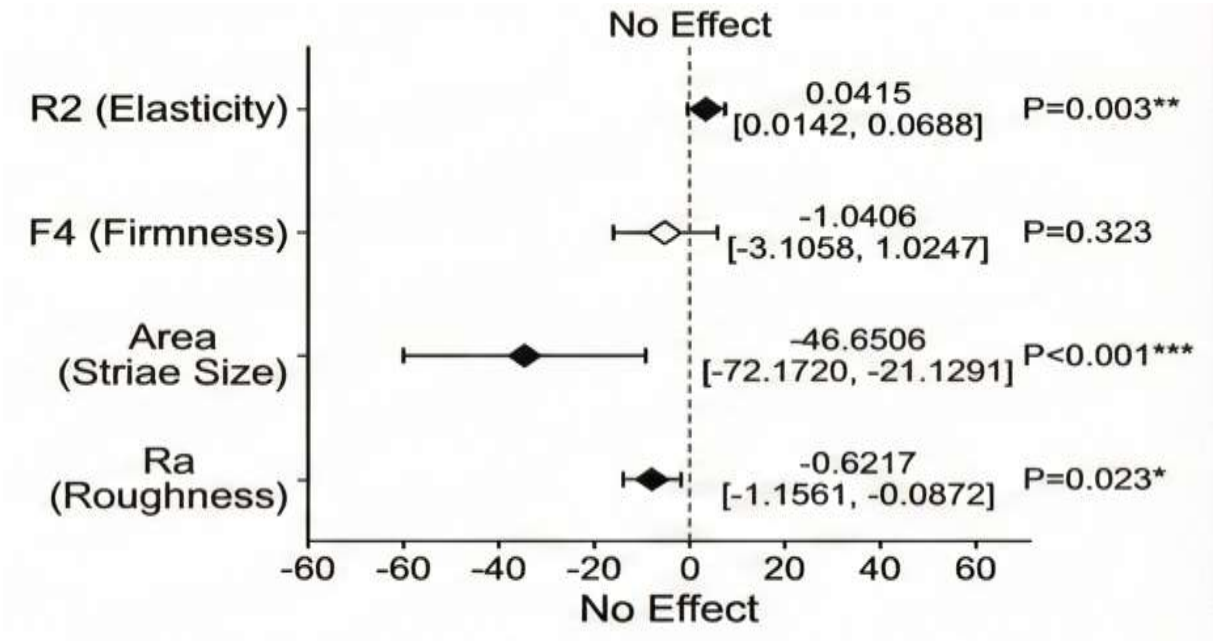

Figure 3: Forest plot displaying treatment effects (Time[W4] × Side[Test] interaction coefficients) for all four biophysical parameters. Horizontal lines represent 95% confidence intervals. Vertical dashed line indicates null effect (coefficient = 0). Parameters showing significant treatment effects (confidence intervals not crossing zero) are displayed with solid markers, while non-significant effects use open markers. R2 (elasticity) shows positive effect indicating improvement; Area and Ra (roughness) show negative effects indicating favorable reduction; F4 shows non-significant trend.

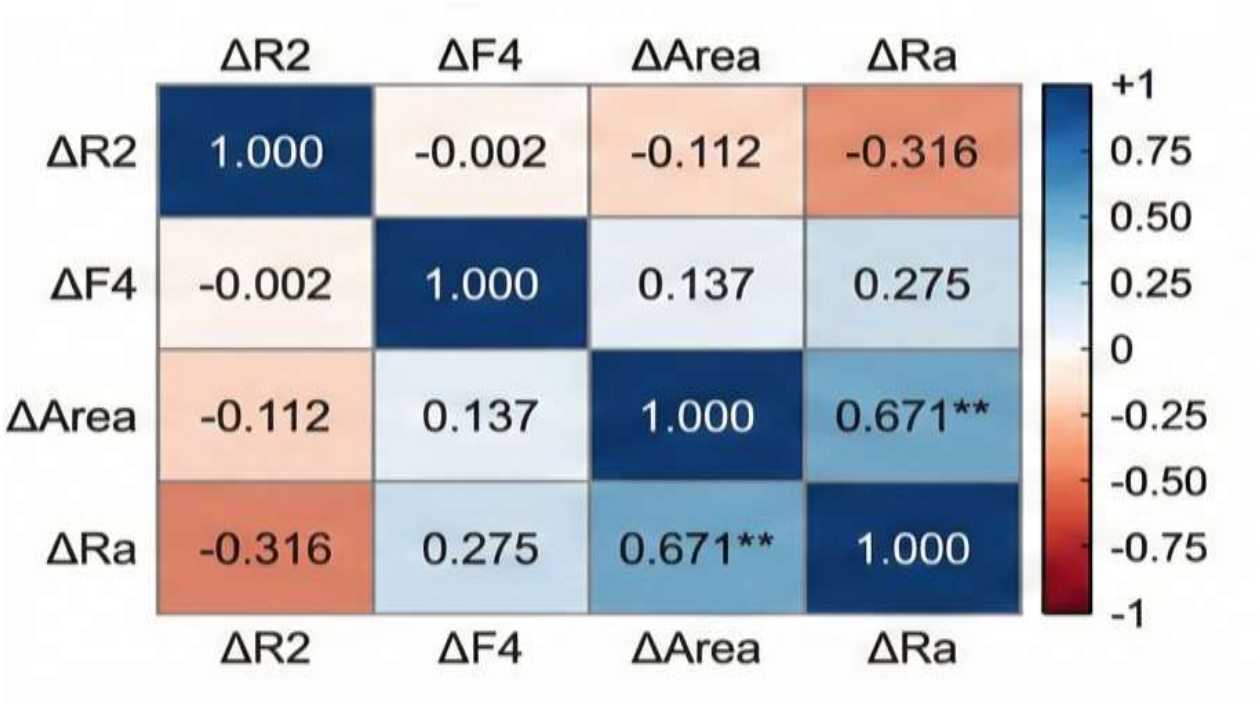

Figure 4: Heatmap visualization of correlation matrix for change scores (Week 4 - Baseline) on test side. Color intensity represents correlation strength: blue indicates positive correlation, red indicates negative correlation. Asterisks denote statistical significance (*P<0.05, **P<0.01).

Table 5: Pearson correlation matrix of change scores (Week 4 - Baseline) on test side

	ΔR2	**ΔF4**	**ΔArea**	**ΔRa**
ΔR2	1.000	-0.002	-0.112	-0.316
ΔF4	-0.002	1.000	0.137	0.275
ΔArea	-0.112	0.137	1.000	0.671
ΔRa	-0.316	0.275	0.671	1.000

Note: Δ denotes change from baseline to week 4. Positive values indicate increase; negative values indicate decrease. For R2, positive Δ is favorable. For F4, Area, and Ra, negative Δ is favorable.

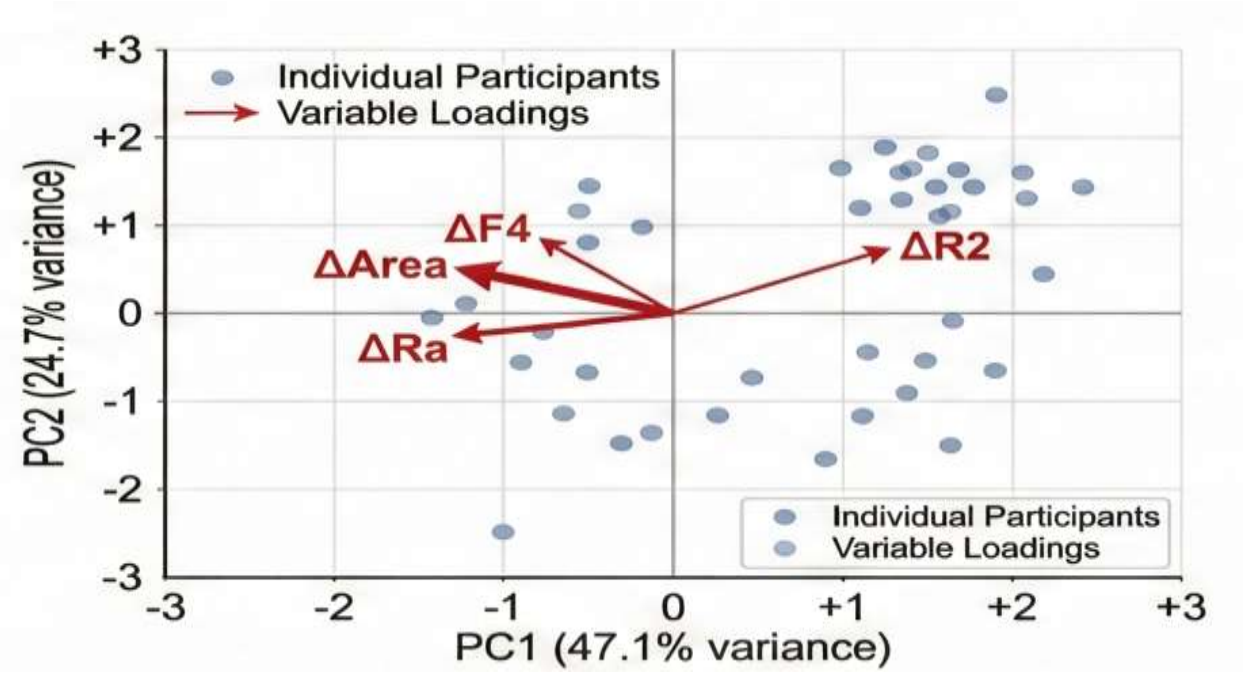

Figure 5: Biplot from principal component analysis showing distribution of individual participants (points) and variable loadings (arrows) in PC1-PC2 space. Red arrows represent change score variables (ΔR2, ΔF4, ΔArea, ΔRa). Individuals positioned in the upper-right quadrant demonstrate high composite improvement across multiple parameters. PC1 (x-axis) explains 47.1% variance; PC2 (y-axis) explains 24.7% variance.

Table 6: Principal component loadings and variance explained

Variable	**PC1 Loading**	**PC2 Loading**
ΔR2 (Elasticity)	0.318	0.717
ΔF4 (Firmness)	-0.304	0.694
ΔArea (Striae Area)	-0.600	0.052
ΔRa (Roughness)	-0.668	-0.022
Variance Explained	47.1%	24.7%
Cumulative Variance	47.1%	71.8%

Note: Loadings indicate the contribution of each variable to the principal component. High absolute loadings (|loading| > 0.5) are highlighted in bold.

clinical variables. No significant correlations were observed with age (r=-0.15, P=0.53), body mass index (r=0.08, P=0.73), time since delivery (r=-0.21, P=0.39), or gestational weight gain (r=0.12, P=0.62), as illustrated for age in Figure 6. Within the studied range of baseline characteristics,

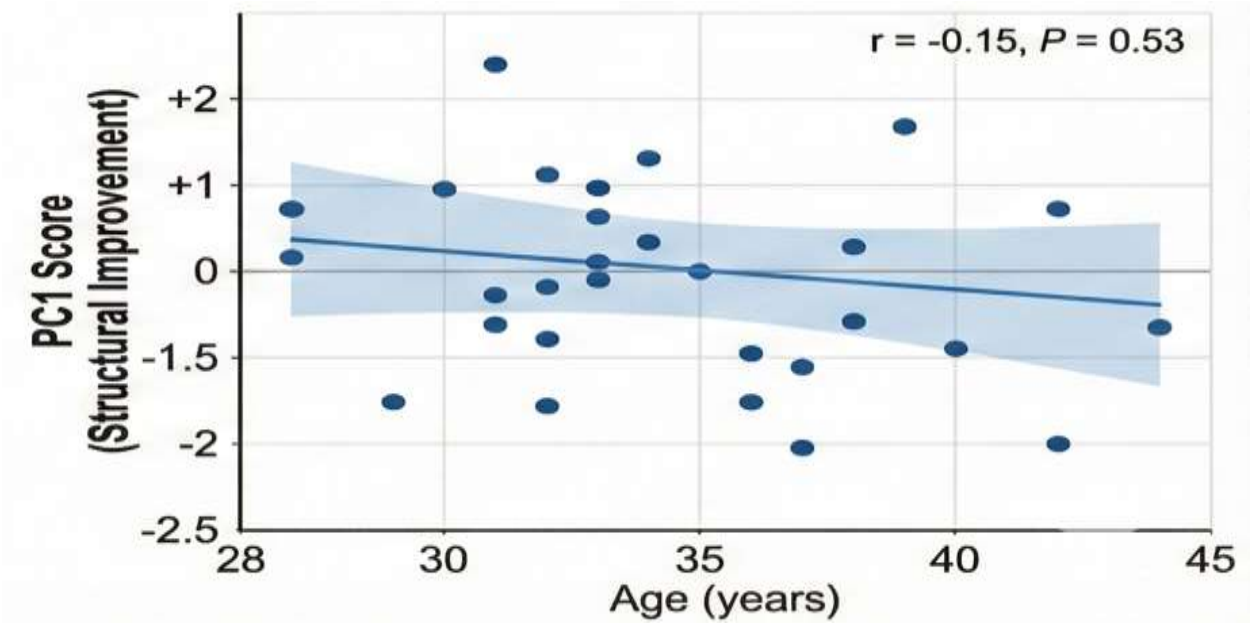

Figure 6: Scatter plot showing relationship between baseline age and PC1 score (composite structural improvement factor). Each point represents one participant. Linear regression line (blue) with 95% confidence interval (shaded region) is superimposed. Correlation coefficient r=-0.15, P=0.53.

response to the serum was therefore relatively consistent.

Safety and tolerability

No serious adverse events were reported during the study. Mild transient erythema at the application site occurred in two participants during the first week and resolved spontaneously without treatment discontinuation. No participant reported pruritus, burning sensation, or systemic symptoms. Overall, the recombinant human collagen serum demonstrated good local tolerability.

Discussion

This prospective, self-controlled clinical study shows that topical recombinant human collagen serum was associated with measurable improvement in several objective characteristics of striae gravidarum-affected skin over 4 weeks. The treated side demonstrated greater gains in elasticity and greater reductions in striae area and surface roughness than the untreated contralateral side. Because the analysis accounted for repeated measurements within participants and adjusted for age and body mass index, the observed differences are best interpreted as treatment-associated changes rather than simple temporal variation.

The observed improvement in elasticity is biologically plausible because striae gravidarum involves disruption and reorganization of dermal collagen and elastic fiber networks.[13] Recombinant human collagen may contribute to tissue recovery through several complementary mechanisms. It can provide a biocompatible extracellular matrix-like substrate, support fibroblast adhesion and proliferation, and promote endogenous matrix remodeling.[14,15,23] These mechanisms are consistent with the gradual separation of elasticity trajectories between the treated and control sides during the study period.

The reduction in visible striae area is clinically relevant because the most important concerns for many postpartum women are the extent and visibility of abdominal striae. Previous reviews have described improvement with procedural treatments such as lasers and microneedling, but such approaches require equipment, specialist expertise, and greater procedural burden.[3,7] In contrast, a topical serum is simpler to integrate into postpartum self-care and may be acceptable for women who prefer non-invasive treatment. The observed area reduction is

consistent with partial remodeling of atrophic striae architecture and improved tissue appearance.[13,24]

Surface roughness decreased on the treated side, indicating smoother skin texture. The strong correlation between area reduction and roughness reduction suggests that visible improvement and surface smoothing occurred together rather than as isolated changes. This coordinated pattern is consistent with a broader remodeling process involving the dermal matrix and skin surface topography.[18,25,26]

The firmness parameter showed a favorable direction of change but did not reach statistical significance. This result should not be interpreted as evidence of absence of effect; rather, firmness is a complex biomechanical outcome influenced by dermal thickness, extracellular matrix organization, hydration, and subcutaneous tissue characteristics. Prior work also indicates that skin mechanical measures are not interchangeable and may respond differently to intervention.[27] A longer treatment period may be required before firmness changes become large enough to detect reliably.

The use of linear mixed-effects models strengthened the analysis by accounting for within-participant correlation and by accommodating incomplete intermediate measurements without discarding participants who completed the primary week 4 assessment.[19,28] This approach is particularly suitable for split-body dermatological studies, in which each participant contributes paired observations over time. The significant time-by-side interactions for elasticity, striae area, and roughness provide more rigorous evidence than isolated before-and-after comparisons.

The principal component analysis added a clinically useful multivariate perspective. The first component captured a structural improvement domain dominated by striae area and roughness, while the second component captured a biomechanical domain dominated by elasticity and firmness.[21,22] This distinction suggests that future studies should not rely on a single endpoint, because postpartum striae improvement may involve separate but related changes in visible morphology and mechanical behavior.

The absence of significant associations between baseline characteristics and composite improvement suggests that treatment-associated improvement was relatively consistent across the enrolled participants. This finding is encouraging for clinical use, although it should be interpreted cautiously because the study sample was small and the ranges of age, postpartum interval, and body mass index were limited. Larger studies could evaluate whether baseline striae severity, skin type, hormonal status, or biomarkers of collagen turnover predict stronger response.

The study has several limitations. The 4-week treatment period was sufficient to detect early improvement, but collagen remodeling can continue for a longer period, and durability after discontinuation was not evaluated.[13] The sample included only postpartum women with abdominal striae, so the findings may not generalize to striae associated with puberty, rapid weight change, or endocrine disorders. The self-controlled design reduced inter-individual variability but did not evaluate the psychological effect of bilateral treatment in routine practice. Histological confirmation was not performed because of ethical considerations, and future work using non-invasive imaging could better characterize the structural changes underlying the observed biophysical improvements.[24]

The results have practical implications for postpartum care. For clinicians, recombinant human collagen serum may represent a non-invasive first-line adjunct for women seeking improvement in striae-related dryness, roughness, and texture. For health policy and service planning, the findings support the value of including evidence-based postpartum skin care counseling within maternal health services, particularly because visible skin changes can affect well-being and body image. The favorable tolerability profile also suggests that the product could be studied further in broader postpartum populations, including lactating women, with appropriate safety oversight.

Future research should focus on confirming these findings in larger, multicenter studies with longer follow-up, standardized patient-reported outcome measures, and objective imaging. Dose-ranging studies could identify the most effective collagen concentration and application schedule, while mechanistic studies could clarify how recombinant human collagen influences fibroblast

activity, dermal matrix remodeling, hydration, and surface topography. Pragmatic trials in routine postpartum settings would help determine real-world adherence, acceptability, cost implications, and implementation barriers.[29]

Strengths and limitations

The main strengths of this study include its prospective self-controlled design, standardized application protocol, blinded objective measurements, use of validated biophysical instruments, and statistical modeling that accounted for repeated measurements. These features reduce measurement bias and improve the precision of treatment-effect estimation. The main limitations are the modest sample size, single-center setting, short follow-up, absence of histological confirmation, and limited assessment of patient-reported outcomes. Taken together, the findings are most appropriately viewed as early clinical evidence supporting further evaluation rather than definitive proof of long-term effectiveness.

Conclusion

In conclusion, the study objective was addressed by demonstrating that recombinant human collagen serum was associated with improved elasticity, reduced striae area, and reduced surface roughness in postpartum women with striae gravidarum. The treatment was well tolerated, and the objective measurements indicate improvement across both visible structural and surface-texture domains. These results support the potential role of recombinant human collagen serum as a practical non-invasive option for postpartum striae gravidarum management and justify larger multicenter trials with longer follow-up.

Conflict of interests

The authors declared no conflict of interest.

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Authors' contributions

Chenxing Li and Jing Chen conceived and designed the study. Chenxing Li, Yan Yao, and Li Zhou recruited participants and collected clinical data. Junguang Hou contributed to study coordination and data management. Chenxing Li and Jing Chen performed the statistical analysis and interpreted the results. Chenxing Li drafted the manuscript, and all authors critically reviewed the manuscript, approved the final version, and agreed to be accountable for the work.

Data availability

The datasets generated and analyzed during the current study are available from the corresponding author on reasonable request, subject to institutional ethics and privacy requirements.

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