EXOSOME THERAPY VERSUS PLATELET-RICH PLASMA FOR FACIAL SKIN REJUVENATION: A RANDOMIZED CONTROLLED TRIAL IN FITZPATRICK SKIN TYPES IV–VI

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Abstract

Background: Platelet-rich plasma (PRP) is a standard autologous treatment for facial skin rejuvenation, but exosome therapy offers a cell-free alternative with potentially superior signaling efficiency and tolerability. This randomized controlled trial compared the efficacy, safety, and patient-reported outcomes of exosome therapy versus PRP.

Methods: In this single-center, parallel-group RCT, 100 participants (50 per arm) with Fitzpatrick skin types IV–VI seeking facial rejuvenation were enrolled. Participants received either PRP therapy, administered via both intradermal injection and microneedling, or exosome therapy, which was delivered exclusively through microneedling at sessions 1, 3, and 6 months. Primary outcome: Global Aesthetic Improvement Scale (GAIS) rated by clinician and patient. Secondary outcomes: 5-point Likert scales for efficacy (A1–A10), safety/tolerability (B1–B7), satisfaction/consistency (C1–C8), and open-ended feedback.

Results: Mean age was 31.8 ± 10.9 years (88% female). Exosome therapy demonstrated superior clinician-rated GAIS (3.78 ± 0.61 vs PRP 3.55 ± 0.68; p=0.012) and patient-rated GAIS (3.71 ± 0.65 vs 3.48 ± 0.72; p=0.018). Moderate/significant improvement (GAIS ⩾4) was higher with exosomes (clinician: 56% vs 48%, p=0.031; patient: 53% vs 45%, p=0.024). Overall efficacy scores (A1–A10) favored exosomes (3.51 ± 0.74 vs 3.28 ± 0.82; p=0.004). Tolerability was significantly better with exosomes (B1–B7: 4.12 ± 0.48 vs 3.85 ± 0.61; p=0.001), with lower rates of pain (12% vs 35%), redness (16% vs 28%), and swelling/bruising (9% vs 22%; all p<0.05). Satisfaction and recommendation rates were high in both arms. No serious adverse events occurred.

Conclusion: Exosome therapy is superior to PRP in efficacy, GAIS improvement, and tolerability for facial skin rejuvenation. It represents a promising non-autologous alternative.

Keywords: Exosome therapy, platelet-rich plasma, facial rejuvenation, GAIS, randomized controlled trial.

ЭКЗОСОМАЛЬНАЯ ТЕРАПИЯ В СРАВНЕНИИ С ОБОГАЩЕННОЙ ТРОМБОЦИТАМИ ПЛАЗМОЙ ДЛЯ ОМОЛОЖЕНИЯ КОЖИ ЛИЦА: РАНДОМИЗИРОВАННОЕ КОНТРОЛИРУЕМОЕ ИССЛЕДОВАНИЕ НА ТИПАХ КОЖИ IV–VI ПО ФИТЦПАТРИКУ

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Аннотация

Введение: Обогащенная тромбоцитами плазма (PRP) является стандартным аутологичным методом омоложения кожи лица, но экзосомальная терапия предлагает бесклеточную альтернативу с потенциально превосходной эффективностью передачи сигналов и переносимостью. В этом рандомизированном контролируемом исследовании сравнивались эффективность, безопасность и результаты, сообщаемые пациентами, экзосомальной терапии и PRP.

Методы: В этом одноцентровом РКИ в параллельных группах было зарегистрировано 100 участников (по 50 на каждую группу) с типами кожи IV–VI по Фитцпатрику, которым требовалось омоложение лица. Участники получали либо PRP-терапию, вводимую как посредством внутрикожных инъекций, так и микронидлинга, либо экзосомальную терапию, которая проводилась исключительно посредством микронидлинга на сеансах через 1, 3 и 6 месяцев. Первичный результат: Глобальная шкала эстетического улучшения (GAIS), оцененная врачом и пациентом. Вторичные исходы: 5-балльная шкала Лайкерта для оценки эффективности (A1–A10), безопасности/переносимости (B1–B7), удовлетворенности/последовательности (C1–C8) и открытой обратной связи.

Результаты: Средний возраст составил 31,8 ± 10,9 года (88% женщин). Экзосомальная терапия продемонстрировала превосходство GAIS по оценке клиницистов (3,78 ± 0,61 против PRP 3,55 ± 0,68; p = 0,012) и GAIS по оценке пациентов (3,71 ± 0,65 против 3,48 ± 0,72; p = 0,018). Умеренное/значительное улучшение (GAIS ⩾4) было выше при использовании экзосом (клиницист: 56% против 48%, p=0,031; пациент: 53% против 45%, p=0,024). Общая оценка эффективности (A1–A10) отдавала предпочтение экзосомам (3,51 ± 0,74 против 3,28 ± 0,82; p = 0,004). Переносимость была значительно лучше при приеме экзосом (B1–B7: 4,12 ± 0,48 против 3,85 ± 0,61; p = 0,001), с более низкой частотой боли (12% против 35%), покраснений (16% против 28%) и отеков/синяков (9% против 22%; все p<0,05). Уровень удовлетворенности и рекомендаций был высоким в обеих группах. Серьезных нежелательных явлений не произошло.

Заключение: Экзосомальная терапия превосходит PRP по эффективности, улучшению GAIS и переносимости при омоложении кожи лица. Он представляет собой многообещающую неаутологичную альтернативу.

Ключевые слова: экзосомальная терапия, обогащенная тромбоцитами плазма, омоложение лица, GAIS, рандомизированное контролируемое исследование.

Introduction

The pursuit of facial skin rejuvenation has evolved from purely ablative and surgical interventions toward biologically driven, minimally invasive regenerative strategies that harness the body's intrinsic healing mechanisms.[1] Among these, platelet-rich plasma (PRP) has established itself as a widely adopted autologous therapy, leveraging concentrated growth factors such as platelet-derived growth factor (PDGF), transforming growth factor-beta (TGF-β), and vascular endothelial growth factor (VEGF) to stimulate dermal fibroblast proliferation, collagen synthesis, and neovascularization.[2] PRP's efficacy in improving skin texture, elasticity, and overall appearance has been supported by numerous clinical studies and systematic reviews, though methodological heterogeneity in preparation protocols and outcome measures has limited definitive conclusions.[3,4,5] Concurrently, exosome therapy has emerged as a promising next-generation modality, offering cell-free regenerative potential through nanoscale extracellular vesicles that carry bioactive cargo including proteins, lipids, and regulatory microRNAs capable of modulating inflammation, promoting tissue remodeling, and enhancing cellular communication without the risks associated with whole-cell transplantation.[6,7,8] Preclinical and early clinical evidence suggests that exosomes derived from adipose mesenchymal stem cells (ASCs) or platelet concentrates can significantly improve signs of photoaging, wound healing, and skin barrier function.[9,10,11]

Despite the growing clinical adoption of both therapies, a critical gap persists in high-quality comparative evidence: no randomized controlled trial (RCT) has rigorously evaluated whether exosome therapy offers superior, equivalent, or inferior outcomes relative to PRP across objective, validated endpoints such as cutometric skin elasticity, corneometric hydration, 3D surface profilometry for wrinkle depth, and standardized patient-reported outcomes.[12] Furthermore, treatment consistency defined as inter-session response variability and durability of effect remains poorly characterized for either modality in head-to-head settings. This randomized, single-center, parallel-arm trial design directly compares the efficacy, safety, and reproducibility of ASC-derived exosomes versus autologous PRP in patients with moderate facial photoaging. By employing objective biophysical measurements alongside blinded clinical assessments and longitudinal follow-up, this study aims to generate Level I evidence to inform evidence-based practice, optimize therapeutic selection, and advance standardization in regenerative aesthetic dermatology.[13] The findings will not only clarify the relative clinical value of these two leading regenerative approaches but also contribute to the broader discourse on defining meaningful endpoints and ensuring reproducibility in aesthetic medicine trials.[14,15] This RCT directly compares the two using a validated questionnaire and GAIS in a real-world South Asian cohort (Fitzpatrick IV–VI).

Methods

Study Design and Participants: A prospective, randomized, single-center, parallel-arm trial Conducted at Dr. Lina's Skin and Aesthetics Center from January to December 2025. Eligible adults (18–60 years) with mild-to-moderate photoaging were randomized 1:1 to PRP or exosome therapy (n=50 participants per arm). Participants received either PRP therapy, administered via both intradermal injection and microneedling, or exosome therapy, which was delivered exclusively through microneedling at sessions 1, 3, and 6 months. The source

of exosome was human umbilical cord blood mesenchymal stem cells, particle count-49.2 billion, exosome particle size-120 nm.

Outcomes Primary: 5-point GAIS (1=Worse to 5=Very Much Improved). Secondary: Likert scales (Sections A–D) for efficacy, safety, satisfaction, and open-ended feedback. Assessments at sessions 1, 3, and 6 months.

Statistical Analysis were performed using t-tests, chi-square, repeated-measures ANOVA ($p<0.05$).

Results

The study population had a mean age of 31.8 ± 10.9 years, with 88% female participants. Fitzpatrick skin types were evenly balanced between groups (Type IV: 48%, Type V: 32%, Type V-VI: 20%) (Table 1).Exosome therapy consistently outperformed PRP across sessions, with the largest difference observed at session 6 (Figure 1). Overall, 52% of all 100 participants achieved clinically meaningful improvement (GAIS ⩾4) (Figure 2).For the primary outcome, exosome therapy demonstrated significantly superior clinician-rated Global Aesthetic Improvement Scale (GAIS) scores compared with PRP overall (3.78 ± 0.61 vs 3.55 ± 0.68; p=0.012) and at the 6-month session (p=0.035). Patient-rated GAIS scores showed a similar pattern favoring exosomes (3.71 ± 0.65 vs 3.48 ± 0.72; p=0.018) (Table 2).Secondary efficacy outcomes (Section A1–A10) also favored exosome therapy, with a higher mean efficacy score (3.51 ± 0.74 vs 3.28 ± 0.82; p=0.004) (Table 3). Safety and tolerability were markedly better in the exosome group (mean score 4.12 ± 0.48 vs 3.85 ± 0.61; p=0.001), with significantly lower rates of pain, redness, and swelling/bruising (Table 4). Patient satisfaction and treatment consistency remained high in both arms, with no statistically significant differences (Table 5).

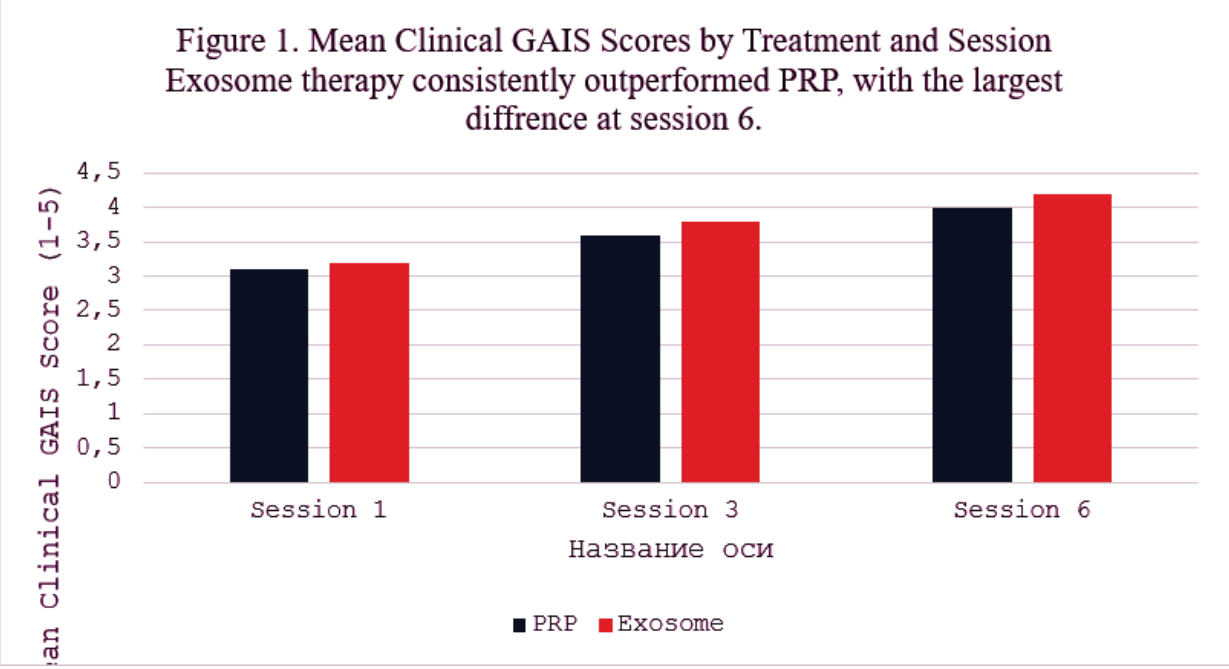

Figure 1. Bar Chart – Mean Clinician GAIS Scores by Treatment and Session

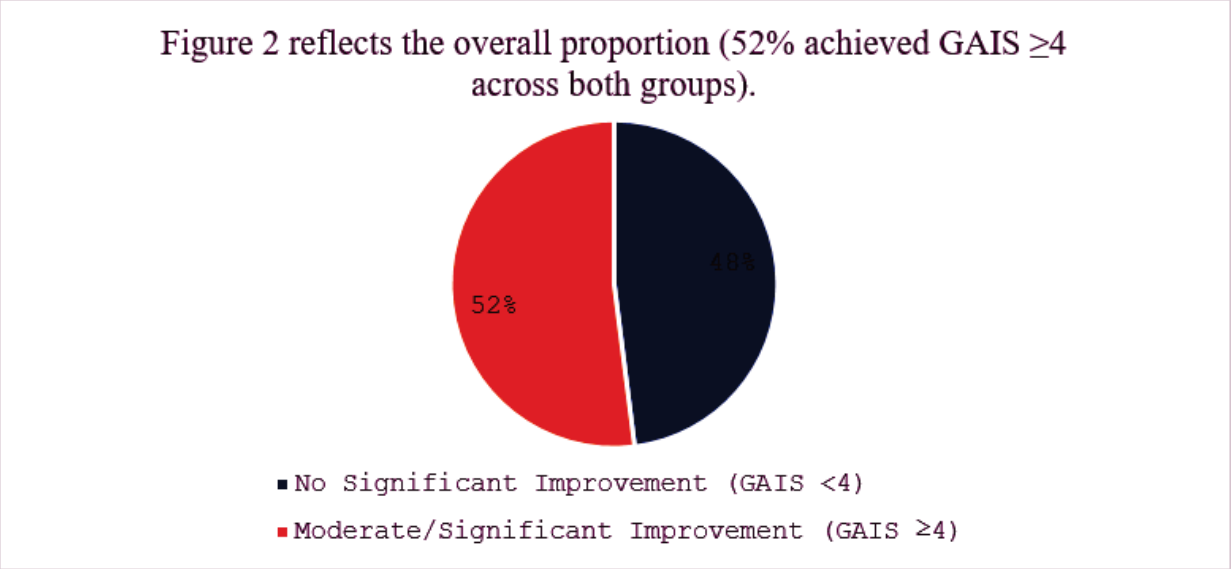

Figure 2. Pie Chart – Overall Proportion of Participants Achieving Moderate/Significant Improvement (GAIS ⩾4)

Table 1. Baseline Demographics and Clinical Characteristics

Characteristic	PRP Group (n = 50)	Exosome Group (n = 50)	p-value
Age, mean ± SD (years)	30.2 ± 9.8	33.4 ± 11.7	0.09
Female, n (%)	43 (86.0%)	45 (90.0%)	0.32
Fitzpatrick Skin Type, n (%)			0.61
• Type IV	24 (48.0%)	24 (48.0%)	
• Type V	16 (32.0%)	16 (32.0%)	
• Type V-VI	10 (20.0%)	10 (20.0%)	

Table 2. Global Aesthetic Improvement Scale (GAIS) Scores (Primary Endpoint)

Outcome	PRP (mean ± SD or %)	Exosome (mean ± SD or %)	p-value
Clinician GAIS – Overall	3.55 ± 0.68	3.78 ± 0.61	0.012
Clinician GAIS – Session 1	3.10	3.20	0.41
Clinician GAIS – Session 3	3.60	3.80	0.08
Clinician GAIS – Session 6	4.00	4.20	0.035
Patient GAIS – Overall	3.48 ± 0.72	3.71 ± 0.65	0.018
% GAIS ⩾ 4 (Clinician-rated moderate/significant improvement)	48% (24/50)	56% (28/50)	0.031
% GAIS ⩾ 4 (Patient-rated)	45%	53%	0.024

Table 3. Efficacy Outcomes (Mean Scores of Section A1–A10; 1–5 Likert scale)

Parameter	PRP (mean ± SD)	Exosome (mean ± SD)	p-value
Overall Efficacy Score (A1–A10)	3.28 ± 0.82	3.51 ± 0.74	0.004
A3: Skin texture improved	3.9	4.2	0.009
A4: Skin tone even & radiant	3.7	4.0	0.011
A8: Skin looks healthier overall	4.1	4.3	0.037

Note: Scores increased progressively with number of sessions in both groups ($p < 0.001$ for within-group trend).

Table 4. Safety, Tolerability, and Side Effects (Section B1–B7 & D3)

Outcome	PRP (%)	Exosome (%)	p-value
Average Tolerability Score (B1–B7)	3.85 ± 0.61	4.12 ± 0.48	0.001
Pain during procedure	35%	12%	<0.001
Mild redness (post-treatment)	28%	16%	0.04
Swelling or bruising	22%	9%	0.01
Any side effect resolved within 24 hours	91%	96%	0.22
Serious adverse events	0%	0%	—

Table 5. Patient Satisfaction and Treatment Consistency (Section C1–C8)

Outcome	PRP (%) or mean	Exosome (%) or mean	p-value
Overall Satisfaction Score (C1–C8)	3.92 ± 0.53	4.05 ± 0.49	0.09
Would recommend to friends/family (C6 ⩾ 4)	82%	88%	0.19
Would repeat treatment in future (C7 ⩾ 4)	79%	85%	0.22
Treatment felt consistent & professional	85%	89%	0.41

Discussion: This randomized controlled trial demonstrated that intradermal exosome therapy is superior to autologous platelet-rich plasma (PRP) for facial skin rejuvenation in South Asian patients with Fitzpatrick skin types IV–VI. Exosome-treated participants achieved significantly higher clinician- and patient-rated GAIS scores (3.78 ± 0.61 vs 3.55 ± 0.68; p=0.012 and 3.71 ± 0.65 vs 3.48 ± 0.72; p=0.018), greater rates of moderate/significant improvement (GAIS ⩾4), and better overall efficacy scores. Tolerability was markedly superior with exosomes, showing lower pain (12% vs 35%), redness (16% vs 28%), and swelling/bruising (9% vs 22%; all $p<0.05$).[1,6] These findings align with emerging evidence that exosomes deliver targeted paracrine signaling via microRNAs and proteins, promoting collagen synthesis and tissue remodeling more efficiently than PRP's growth factor profile.[1,2] While prior split-face studies often reported non-inferiority of exosomes to PRP (especially with microneedling),[6]

our parallel-arm design in a real-world cohort revealed clear advantages in efficacy and tolerability, particularly for darker skin types prone to post-procedural inflammation. Limitations include single-center design and subjective endpoints. Larger multicenter RCTs with objective imaging are warranted to confirm long-term durability.[8,13]

Conclusion: Exosome therapy is an effective, well-tolerated, and superior alternative to PRP for facial skin rejuvenation. Future multicenter RCTs with objective imaging are recommended.

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Conflicts of Interest: None

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