Research Article

Clinical Response and Safety of Platelet-Rich Fibrin Matrix in Periorbital Wrinkles and Hyperpigmentation: A Prospective Longitudinal Study

Sanman Mithani, Ujjwal Kumar, Shashank Bhargava, Krishnendra Varma, Aishwarya Mahadik*

Introduction: Periorbital wrinkles and hyperpigmentation are frequent aesthetic concerns with multifactorial pathogenesis and variable response to conventional therapy. Platelet-rich fibrin matrix (PRFM) is an autologous platelet concentrate with a fibrin scaffold that may support dermal remodeling.

Methods: A prospective longitudinal interventional study was conducted in 35 recruited patients aged more than 30 years with visible periorbital wrinkles and/or hyperpigmentation. PRFM was prepared from 15 mL of venous blood by immediate centrifugation at 700 rpm for 5 minutes and injected into the subdermal periorbital plane. Four monthly sittings were administered, followed by final assessment 3 months after the last sitting. Serial clinical grading, baseline-final scores, categorical improvement, complete clearance, and side effects were recorded. Friedman and Wilcoxon signed-rank tests were applied.

Results: At baseline, wrinkles were moderate in 18 (51.43%) and severe in 17 (48.57%) patients, while hyperpigmentation was moderate in 16 (45.71%) and severe in 19 (54.29%) patients. Median wrinkle score improved from 2 (IQR, 2-3) to 1 (IQR, 1-2), and median hyperpigmentation score improved from 3 (IQR, 2-3) to 2 (IQR, 1-2) at final follow-up (both $p < 0.001$). All patients showed one-grade improvement, but complete clearance was not observed. Adverse effects were mild and transient.

Conclusion: In this uncontrolled cohort, PRFM was associated with progressive one-grade reductions in the ordinal severity of periorbital wrinkles and hyperpigmentation, with only mild, transient adverse effects. Controlled studies incorporating blinded, objective outcome assessment are required to establish comparative efficacy and durability.

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Introduction

Cutaneous ageing has prominent expression on the face, where loss of dermal matrix support, reduced collagen synthesis, collagen fragmentation, elastotic change, and impaired repair mechanisms manifest as fine lines, wrinkles, textural coarsening, and uneven pigmentation.[1] The periorbital region is particularly vulnerable because eyelid skin is thin, has limited subcutaneous support, and is continuously influenced by blinking and facial expression.[2]

Periorbital hyperpigmentation is another common cosmetic concern and may arise from pigmentary, vascular, structural-shadowing, post-inflammatory, or mixed mechanisms.[3,4]

Conventional management includes photoprotection, topical depigmenting agents, chemical peels, energy-based devices, fillers, and combination approaches; however, response may be slow, incomplete, costly, or limited by tolerability and pigmentary risk near the eyes.[5]

PRFM entraps platelets within a three-dimensional fibrin scaffold, enabling gradual local release of platelet-derived mediators. These mediators may support fibroblast activity, collagen synthesis, angiogenesis, and extracellular-matrix remodelling, thereby improving dermal texture and softening wrinkles. Enhanced dermal support and microvascular remodelling may also reduce vascular and structural contributors to periorbital darkness, although a direct melanocyte-suppressive effect has not been established.[6-9]

Evidence specific to periorbital rejuvenation with PRFM remains limited, and recent reviews emphasize the need for better standardization of protocols, outcome

Department of Dermatology, Venereology and Leprosy, R.D. Gardi Medical College, Ujjain, Madhya Pradesh, India.

Correspondence to: Sanman Mithani, Department of Dermatology, Venereology and Leprosy, R.D. Gardi Medical College, Ujjain, Madhya Pradesh, India, E-mail: mithanisanman65@gmail.com

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measures, and safety reporting.[6-9] The present study was undertaken to evaluate the clinical response and safety of PRFM in patients with periorbital wrinkles and hyperpigmentation using serial grading across a structured treatment course.

Materials and Methods

This prospective longitudinal interventional study was conducted in the dermatology outpatient department of a tertiary care teaching hospital in central India. The study was approved by the Institutional Ethics Committee (IEC Ref. No. PG/DERMATOLOGY/17/2024; approval dated 09/05/2024). Written informed consent was obtained from all participants, and the study procedures were conducted in accordance with institutional ethical requirements. Separate written consent was obtained for publication of the clinical photographs.

Patients attending the outpatient department with clinically visible periorbital wrinkles and/or periorbital hyperpigmentation were screened. Consecutive eligible and consenting patients were recruited over the one-year study period. Based on anticipated outpatient attendance and consent rates, a feasible enrolment range of 30 to 35 participants was specified prospectively; enrolment concluded after 35 participants had been included. All 35 completed the four-sitting treatment schedule and final follow-up.

Patients aged more than 30 years who were willing to participate and had visible periorbital wrinkles and/or hyperpigmentation were included. Patients with unrealistic expectations, diabetes mellitus, collagen vascular disease, pregnancy or lactation, local infection at the intended procedure site, platelet dysfunction syndrome, critical thrombocytopenia, connective tissue disorders, current use of immunomodulatory or anticoagulant drugs, or ongoing topical or other treatment for the same condition were excluded.

Baseline evaluation included demographic details, clinical history, symptom duration, family history, relevant comorbidities, general and dermatological examination, and baseline grading of wrinkle and hyperpigmentation severity. Clinical visibility was defined as a grade of at least 1 on the study rubric. The category anchors were adapted from the Fitzpatrick wrinkle classification and the clinical pigmentation grading described by Sheth *et al*.[4,10] Periorbital wrinkles were classified as mild (class I: fine wrinkles), moderate (class II: fine-to-moderate-depth wrinkles with a moderate number of lines), or severe (class III: fine-to-deep wrinkles with numerous lines, with or without redundant folds). Periorbital hyperpigmentation was graded relative to adjacent facial skin as absent (no discernible contrast), mild (faint contrast), moderate (clearly pronounced pigmentation), or severe (deep dark pigmentation). For analysis, absent, mild, moderate, and severe were coded 0, 1, 2, and 3, respectively; higher scores denoted greater severity. A one-grade response was an exact one-category reduction from baseline, whereas complete clearance was defined as a final score of 0. Baseline investigations included complete blood count, bleeding time, clotting time, and HIV tri-dot testing.

For each sitting, venous blood was collected from the brachial vein under aseptic precautions after reviewing drug history. A total of 15 mL of blood was distributed equally among three sterile 5 mL collection tubes and centrifuged immediately at 700 rpm for 5 minutes. The gel-like plasma fraction was withdrawn aseptically with a sterile transfer cannula, leaving approximately 1-cm above the tube, transferred into a sterile 5 mL syringe, and subsequently divided among 1-mL syringes through sterile connections. After topical or local anaesthesia and povidone-iodine skin preparation, approximately 3 mL of PRFM in total was administered to the clinically involved periorbital wrinkle and hyperpigmented areas in the subdermal plane.

Each participant received four sittings at monthly intervals. Clinical response was assessed after each sitting, and the final evaluation was performed 3 months after the fourth sitting. Both outcome domains were graded at each prespecified assessment using the ordinal definitions above. Clinical grading was performed by the treating investigator; neither participants nor the assessor were blinded. The primary efficacy assessment included serial change in clinical grade and baseline-final severity score for periorbital wrinkles and hyperpigmentation. Final categorical improvement and complete clearance were also recorded. Side effects during or after each sitting were documented as the safety outcome.

Data were analyzed using SPSS version 23.0. Continuous variables were summarized as mean ± standard deviation or median with interquartile range, as appropriate. Categorical variables were expressed as frequency and percentage. Serial ordinal changes were analyzed using the Friedman test, and baseline-final severity score comparisons were analyzed using the Wilcoxon signed-rank test. A *p-value* <0.05 was considered statistically significant.

Results

The mean age of the participants was 46.97 9.93 years, with an age range of 31 to 64 years. The largest age groups were 31 to 40 years and 41 to 50 years, each comprising

11 (31.43%) patients. Females constituted 24 (68.57%) patients. The mean duration of symptoms was 28.09 ± 15.41 months, ranging from 8 to 60 months. Baseline demographic and clinical characteristics are summarized in Table 1.

At baseline, no patient had mild periorbital wrinkling or mild hyperpigmentation. Periorbital wrinkles were moderate in 18 (51.43%) patients and severe in 17 (48.57%) patients. Periorbital hyperpigmentation was moderate in 16 (45.71%) patients and severe in 19 (54.29%) patients.

A progressive reduction in periorbital wrinkle severity was observed across serial assessments (Figure 1). Severe wrinkles decreased from 17 (48.57%) patients at baseline to 10 (28.57%) after the first sitting and 2 (5.71%) after the second sitting; no patient remained in the severe grade from the third sitting onward. At final follow-up, 18 (51.43%) patients had mild wrinkles and 17 (48.57%) had moderate wrinkles. The serial change in wrinkle severity was statistically significant (Friedman test, $\chi^2 = 134.50$, $p < 0.001$).

Table 1: Baseline demographic and clinical characteristics of the study participants (N = 35)

Characteristic	*Category*	*n (%)*
Age group (years)	31-40	11 (31.43%)
	41-50	11 (31.43%)
	51-60	9 (25.71%)
	>60	4 (11.43%)
Sex	Female	24 (68.57%)
	Male	11 (31.43%)
Socioeconomic status	Upper	6 (17.14%)
	Middle	20 (57.14%)
	Lower	9 (25.71%)
Occupation	Homemaker	9 (25.71%)
	Shopkeeper	7 (20.00%)
	Teacher	7 (20.00%)
	Farmer	6 (17.14%)
	Office worker	6 (17.14%)
Sleep pattern	Sound	23 (65.71%)
	Disturbed	12 (34.29%)
Family history of similar illness	Absent	18 (51.43%)
	Present	17 (48.57%)
Relevant comorbidities	None	22 (62.86%)
	Hypertension	8 (22.86%)
	Asthma	5 (14.29%)
Duration of symptoms	<12 months	4 (11.43%)
	12-36 months	21 (60.00%)
	>36 months	10 (28.57%)

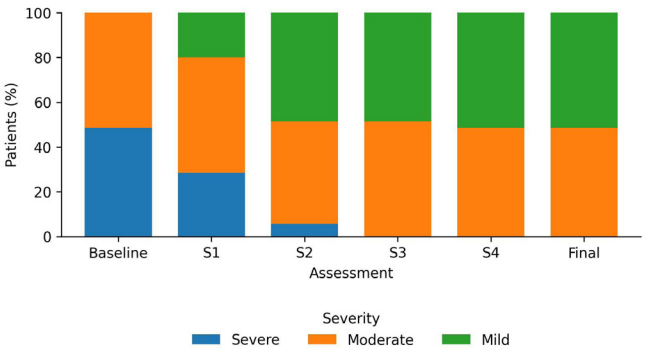

Figure 1: Serial distribution of periorbital wrinkle severity from baseline to final follow-up

Periorbital hyperpigmentation also showed progressive improvement over the treatment course (Figure 2). Severe hyperpigmentation decreased from 19 (54.29%) patients at baseline to 9 (25.71%) after the first sitting and 5 (14.29%) after the second sitting; no patient remained in the severe grade from the third sitting onward. At final follow-up, 16 (45.71%) patients had mild hyperpigmentation and 19 (54.29%) had moderate hyperpigmentation. The serial change in hyperpigmentation severity was statistically significant (Friedman test, $\chi^2 = 125.46$, $p < 0.001$).

Median severity scores for both outcome domains improved significantly at final follow-up (Table 2). The median wrinkle severity score decreased from 2 (IQR, 2-3) at baseline to 1 (IQR, 1-2) at final follow-up. The median hyperpigmentation severity score decreased from 3 (IQR, 2-3) at baseline to 2 (IQR, 1-2) at final follow-up.

All 35 enrolled participants completed all four sittings and the final assessment; both efficacy analyses therefore comprised 35 paired observations, with no losses to follow-up, missing efficacy assessments, or imputed

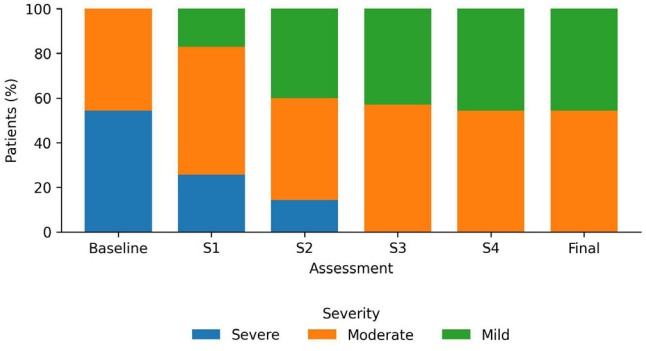

Figure 2: Serial distribution of periorbital hyperpigmentation severity from baseline to final follow-up

Table 2: Baseline-final severity score comparison and final clinical response (N = 35)

Outcome	*Baseline median severity score (IQR)*	*Final median severity score (IQR)*	*Final clinical response n (%)*	*p-value*
Periorbital wrinkles	2 (2-3)	1 (1-2)	One-grade improvement: 35 (100.00%) Complete clearance: 0 (0.00%)	<0.001
Periorbital hyperpigmentation	3 (2-3)	2 (1-2)	One-grade improvement: 35 (100.00%) Complete clearance: 0 (0.00%)	<0.001

IQR: interquartile range. Baseline-final comparisons were analyzed using Wilcoxon signed-rank test.

Table 3: Incidence and type of side effects across sittings (N = 35)

Side effect	*Sitting 1 n (%)*	*Sitting 2 n (%)*	*Sitting 3 n (%)*	*Sitting 4 n (%)*
None	23 (65.71%)	33 (94.29%)	32 (91.43%)	35 (100.00%)
Mild erythema	7 (20.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Mild edema	5 (14.29%)	1 (2.86%)	0 (0.00%)	0 (0.00%)
Mild pain	0 (0.00%)	1 (2.86%)	3 (8.57%)	0 (0.00%)

values. At final follow-up, all 35 (100.00%) patients demonstrated one-grade categorical improvement in both outcome domains. Among patients with periorbital wrinkles, all 17 patients with severe baseline wrinkles improved to moderate grade, while all 18 patients with moderate baseline wrinkles improved to mild grade. Among patients with periorbital hyperpigmentation, all 19 patients with severe baseline pigmentation improved to moderate grade, while all 16 patients with moderate baseline pigmentation improved to mild grade. Complete clearance was not observed in any patient at final follow-up. No participant was a nonresponder or demonstrated a two-grade response; every observed final transition was an exact one-grade reduction.

The safety profile across treatment sittings is presented in Table 3. After the first sitting, mild erythema was recorded in 7 (20.00%) patients and mild edema in 5 (14.29%) patients. By the second sitting, 33 (94.29%) patients had no adverse effect, while mild edema and mild pain were recorded in one patient each. Mild pain was recorded in 3 (8.57%) patients after the third sitting. No adverse effect was recorded after the fourth sitting, and no serious or delayed adverse event was documented.

Discussion

The present study demonstrated progressive and statistically significant improvement in both periorbital wrinkles and periorbital hyperpigmentation after four monthly sittings of PRFM. Severe grades disappeared by the third sitting for both outcome domains, and the improvement was maintained at the final assessment 3 months after the fourth sitting. All patients achieved one-grade improvement, although complete clearance was not achieved in any patient. These findings suggest that PRFM acts primarily as a severity-reducing and remodeling modality rather than a procedure producing complete disappearance of periorbital ageing signs.

The cohort predominantly consisted of middle-aged adults, with a mean age of 46.97 ± 9.93 years, and women formed 68.57% of the sample. This profile is biologically and clinically plausible because intrinsic ageing, photodamage, collagen fragmentation, and soft-tissue changes become more visible in the periorbital region during midlife, while cosmetic concerns around the eyes often prompt earlier consultation among women. Similar treatment-seeking age profiles have been reported in platelet-based periorbital and facial rejuvenation studies.[11-15]

The serial improvement in wrinkles is consistent with the biological rationale of PRFM. A fibrin-based platelet matrix may provide a scaffold for gradual mediator release, fibroblast activity, collagen remodeling, and tissue repair.[6,8] Mahmoodabadi *et al*. reported significant improvement in periorbital wrinkles after a single PRFM session, with objective reduction in tissue volume scores at 12 weeks.[11] Sclafani also reported persistent improvement in deep nasolabial folds after PRFM injection, supporting the concept that platelet-fibrin matrices may produce more than transient filling effects.[16] Atsu *et al*. reported a short-term advantage of injectable PRF over PRP for canthal smoothness and wrinkles at 3 months.[17] Compared with these studies, the present four-sitting protocol demonstrated a clear cumulative clinical pattern across serial visits.

Hyperpigmentation also improved progressively. This finding is clinically relevant because periorbital darkness often has mixed pigmentary, vascular, structural, and inflammatory components.[3,5] Platelet-derived products

may improve dermal quality, microcirculation, tissue hydration, and local repair, which may reduce the visual impact of periorbital darkness even when complete pigment clearance is not achieved.[7,9] Mehryan *et al*. found improvement in infraorbital color homogeneity after PRP but not significant change in wrinkle volume, while Budania *et al*. reported quality-of-life improvement with PRP in periorbital hyperpigmentation.[13,18] The present findings indicate that a repeated PRFM protocol may provide clinically meaningful benefit across both textural and pigmentary domains.

The safety profile was favorable. Adverse effects were limited to mild erythema, mild edema, and mild pain, and no serious, persistent, or delayed adverse event was recorded. This is concordant with available evidence on PRF/PRFM and PRP-based aesthetic procedures, where reported adverse effects are usually transient local reactions.[9,11,19] Nevertheless, the periorbital region remains anatomically sensitive, and safe practice requires careful patient selection, asepsis, conservative injection volumes, and appropriate injection plane. Dermatology recommendations for platelet-rich fibrin also emphasize protocol standardization and procedural caution.[20]

This study adds practical clinical data by assessing both major periorbital concerns together, applying a structured four-session regimen, documenting serial response, and recording safety across sittings. The complete absence of severe grades from the third sitting onward is a useful clinical observation for treatment counseling. However, the absence of complete clearance is equally important and supports realistic counseling that PRFM may soften and downgrade periorbital changes rather than fully erase them.

The findings should be interpreted in view of important limitations. The sample size was small, and the study did not include a control or comparator arm; therefore, comparative efficacy against other modalities cannot be inferred. Follow-up was limited to 3 months after the final sitting, so long-term durability and the need for maintenance sessions could not be established. Objective imaging-based measures and patient satisfaction scales were not incorporated, which may be useful in future controlled studies.

Conclusion

PRFM was associated with progressive, statistically significant, and clinically visible improvement in periorbital wrinkles and hyperpigmentation. All patients achieved one-grade categorical improvement, severe grades were absent from the third sitting onward, and no serious adverse events occurred. PRFM appears to be a useful autologous and minimally invasive option for periorbital rejuvenation, best understood as a regenerative severity-reducing treatment rather than a modality producing complete clearance.

Limitations

The study was limited by its small sample size, absence of a control or comparator group, and relatively short follow-up period. Future studies should include larger controlled cohorts, longer follow-up, standardized objective imaging, and patient-reported outcome measures to clarify durability and comparative effectiveness. Outcome grading was performed by an unblinded treating assessor; consequently, observer bias cannot be excluded.

Ethical Approval

Institutional Ethics Committee approval was obtained (IEC Ref. No. PG/DERMATOLOGY/17/2024; date of approval: 09/05/2024).

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Conflict of Interest

None declared.

Author Contribution

Dr. Sanman Mithani - Concept and design of study, literature search, clinical study, data acquisition, data analysis, statistical analysis, manuscript preparation, manuscript editing, manuscript review, and final approval of the version to be published.
Dr. Ujjwal Kumar - Concept and design of study, definition of intellectual content, clinical supervision, data interpretation, manuscript editing, manuscript review, and final approval of the version to be published. Dr. Ujjwal Kumar will act as guarantor for the work.
Dr.Shashank Bhargava contributed to the study design, interpretation of data, and critical revision of the manuscript for important intellectual content.
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Dr.Aishwarya Mahadik contributed to the conceptualization of the study, supervised the work, and reviewed and approved the final manuscript.

The manuscript has been read and approved by all authors, the requirements for authorship have been met, and the manuscript represents honest work.

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