

Research Article**Three-dose intra-articular platelet-rich plasma versus single-dose hylan G-F 20 for symptomatic knee osteoarthritis: a randomized comparative study****Rasheed Ahmed Bhatti¹, Syed Muhammad Azfar², Nizam Ahmed³, Lachman Das Maheshwari⁴, Sajjad Hussain Bhatti⁵, Sijad Ahmed Mahar⁶**

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Abstract**Background**

Knee osteoarthritis (OA) is a common cause of pain and functional limitation. Platelet-rich plasma (PRP) and hyaluronic-acid viscosupplementation are used as intra-articular treatments, but comparative results vary across studies and protocols.

Objective

To compare pain and functional outcomes after a three-injection PRP regimen and a single injection of hylan G-F 20 in patients with symptomatic radiological grade II–III knee OA.

Methods

This randomised, parallel-group comparative study was conducted at Bilawal Medical College for boys, Liaquat University of Medical and Health Sciences, Jamshoro, Pakistan, from May 2025 to May 2026. The manuscript reports 120 participants allocated

1:1 to three intra-articular autologous PRP injections at four-week intervals (n=60) or one 6-mL injection of hylan G-F 20 (Synvisc-One; n=60). Pain was measured using a 0–10 visual analogue scale (VAS), and

symptoms/function using the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), at baseline and months 1, 2, 4, 5, 6 and 9. The original randomisation records, patient-level dataset and detailed intervention records were unavailable for this revision. Consequently, randomisation procedures, allocation concealment, PRP composition, participant flow and reported analyses could not be independently verified. The trial was not registered in a public registry.

Results

The manuscript-reported baseline characteristics were similar between groups. Both groups showed lower mean VAS and WOMAC scores during follow-up. Reported between-group differences favoured the three-dose PRP regimen from month 4 onwards. At month 6, the reported mean difference (PRP minus hylan G-F 20) was –1.1 points for VAS (95% CI –1.4 to –0.8) and –9.0 points for WOMAC (95% CI –11.4 to –6.6). These estimates are reproduced from the supplied manuscript and have not been recalculated from participant-level data.

Adverse events were not systematically recorded, and the completeness of follow-up could not be independently confirmed.

Conclusion

The supplied summary results suggest greater improvement in pain and function with the three-dose PRP regimen than with a single hylan G-F 20 injection from approximately month 4. Because treatment schedules differed and the underlying dataset and methodological records were unavailable for verification, the findings should be interpreted as a comparison of two regimens rather than evidence of the biological superiority of PRP. Safety and attrition cannot be assessed reliably from the available information.

Keywords: knee osteoarthritis; platelet-rich plasma; hylan G-F 20; hyaluronic acid; intra-articular injection; WOMAC; visual analogue scale

Introduction

Osteoarthritis is a leading cause of pain and disability and affects the whole joint, including articular cartilage, subchondral bone, synovium, ligaments and periarticular muscles [1–3]. Knee OA is associated with reduced mobility, impaired daily activities and a substantial burden for patients and health services. Established management includes education, exercise, weight management where appropriate, and selected pharmacological treatments. Intra-articular interventions may be considered for some patients whose symptoms remain troublesome despite conservative management, although recommendations differ between guidelines [4,5].

Hyaluronic acid (HA) contributes to the viscoelastic properties of synovial fluid. Viscosupplementation aims to improve joint lubrication and symptom control by injecting an HA preparation into the joint [6]. Hylan G-F 20 is a cross-linked hyaluronan product available as a single 6-mL injection. Evidence regarding the magnitude and clinical importance of benefit from viscosupplementation remains mixed, and guideline recommendations vary [4,5,7,8].

Platelet-rich plasma is an autologous blood product containing a higher platelet

concentration than peripheral blood, although its composition varies with the preparation system and protocol [9]. Platelets release biologically active mediators, and experimental work has proposed anti-inflammatory and matrix-related effects in osteoarthritic tissues [22]. These mechanisms were not measured in the present study and should not be taken as demonstrated clinical mechanisms.

Clinical trials comparing PRP with HA have reported mixed results. Differences in patient selection, OA severity, PRP preparation, leukocyte content, injection number, HA formulation and follow-up may contribute to heterogeneity [12–21]. In particular, comparing multiple PRP injections with a single HA injection evaluates two treatment regimens; it cannot isolate the effect of the product from the effect of injection frequency. This study compared a three-dose PRP regimen with a single-dose hylan G-F 20 regimen in patients with symptomatic grade II–III knee OA, using VAS and WOMAC outcomes over nine months.

Methods

Study design and setting

The study is described in the supplied manuscript as a randomised, parallel-group comparative study conducted at Bilawal Medical College / Liaquat University of Medical and Health Sciences, Jamshoro, Pakistan, from May 2025 to May 2026. The report is presented transparently using the information available in the supplied version. The original protocol, study dataset and methodological records were not available to the revising author; statements below therefore distinguish reported information from information that could not be verified.

Participants and eligibility

The supplied manuscript states that participants had symptomatic knee OA of radiological grade II or III and that grade IV disease was excluded. It does not provide a complete list of inclusion and exclusion criteria, the diagnostic criteria used, or the radiographic grading system. These details could not be verified and must be retrieved from the original protocol or clinical records

before submission. No additional eligibility criteria have been inferred.

Allocation and sample size

The manuscript reports that 120 participants were allocated in a 1:1 ratio, with 60 participants in each group. The method used to generate the random sequence, any restrictions such as blocking or stratification, allocation concealment, and the roles of the personnel generating the sequence, enrolling participants and assigning treatment were not documented in the material available for this revision. These details cannot be reconstructed. No a priori sample-size calculation was performed according to the supplied manuscript; therefore, the study should not be described as adequately powered on the basis of a prospective calculation.

Interventions

PRP group: Participants were reported to receive three intra-articular injections of autologous PRP at four-week intervals. PRP was prepared from peripheral venous blood according to an institutional protocol. The blood volume collected, anticoagulant, centrifugation system and settings, number of centrifugation steps, activation method, final injection volume, platelet concentration, leukocyte content and red-cell contamination were not reported in the supplied manuscript and could not be verified.

Hylan G-F 20 group: Participants were reported to receive one 6-mL intra-articular injection of hylan G-F 20 (Synvisc-One). No additional intra-articular injection was reported as part of the study intervention.

Both interventions were reported to be administered using aseptic technique. The injection approach and whether ultrasound guidance or landmark guidance was used were not recorded. Treatment fidelity and whether all allocated injections were received could not be independently confirmed.

Outcomes and follow-up

The reported outcomes were pain measured on a 0–10 VAS (higher scores indicate more pain) and symptoms/function measured using the WOMAC index (higher scores indicate worse symptoms). Measurements were reported at baseline and at months 1, 2, 4, 5, 6

and 9 after the first injection. The supplied manuscript does not identify a single prespecified primary outcome time point. The version supplied reports $n=60$ per group at all time points, but source records were unavailable to verify participant-level completeness, missing data, or whether the same participants contributed to every assessment.

Blinding and co-interventions

The supplied manuscript does not document whether participants, treating clinicians or outcome assessors were blinded. It also does not provide sufficient information about analgesic use, exercise, physiotherapy, other treatments or other co-interventions during follow-up. These items could not be verified and are potential sources of performance and measurement bias.

Subgroup analyses

The supplied manuscript describes exploratory subgroup analyses by sex, radiological grade (II versus III) and BMI category ($18.6\text{--}25$ versus >25 kg/m²). Subgroup-specific sample sizes, estimates, confidence intervals and formal treatment-by-subgroup interaction tests were not available. Accordingly, subgroup findings are retained only as exploratory descriptions; they do not establish treatment-effect modification.

Ethics and trial registration

The supplied manuscript states that the study was approved by the hospital ethics committee and that written informed consent was obtained. The ethics approval number was unavailable. The approval letter and date should be retrieved and checked before submission. The study was not registered in a public trial registry, according to the supplied manuscript.

Statistical analysis

The supplied manuscript reports analysis using SPSS version 26.0. Continuous variables were described as mean $\pm$ standard deviation and categorical variables as counts and percentages. It reports independent-samples t-tests for between-group comparisons at individual time points and chi-square tests for categorical baseline characteristics, with mean differences and 95% confidence intervals calculated from

group means and standard deviations. The original dataset and analysis output were unavailable; calculations, assumptions, denominators, p-values and confidence intervals could not be independently reproduced.

The supplied analysis did not model within-participant repeated measurements, and p-values at individual time points were not adjusted for multiple comparisons. The reported time-point analyses should therefore be treated as unadjusted and descriptive, with an increased risk of false-positive findings. No new statistical analyses, interaction tests or multiplicity corrections have been fabricated for this revision. A reanalysis of the original participant-level dataset by an appropriately qualified statistician is recommended before submission.

Results

Participant characteristics and flow

The supplied manuscript reports that 120 participants were randomised, 60 to each group, and states that outcome data were available for all 120 participants at each time point. Because the original enrolment log, follow-up records and dataset were unavailable, these numbers could not be independently verified. The number screened, excluded before randomisation, receiving the allocated intervention, completing each treatment, withdrawing, or included in each analysis is not available. A complete CONSORT flow diagram cannot responsibly be reconstructed from the information supplied and must be completed from original records before submission.

Characteristic	PRP (n=60)	Hylan G-F 20 (n=60)	Reported p-value
Age, years, mean $\pm$ SD	52.4 $\pm$ 8.7	51.8 $\pm$ 9.1	0.71
Male, n (%)	27 (45.0)	26 (43.3)	0.85
Female, n (%)	33 (55.0)	34 (56.7)	0.85
BMI, kg/m ² , mean $\pm$ SD	27.1 $\pm$ 3.8	26.8 $\pm$ 3.6	0.66
OA grade II, n (%)	32 (53.3)	34 (56.7)	0.72
OA grade III, n (%)	28 (46.7)	26 (43.3)	0.72

Table 1. Baseline characteristics as reported in the supplied manuscript. Values have not been independently verified against source data.

Pain outcomes

The supplied manuscript reports a baseline mean VAS of 7.1 $\pm$ 0.9 in the PRP group and 7.0 $\pm$ 0.8 in the hylan G-F 20 group. Mean VAS scores were reported to decrease in both groups. The reported group means, standard deviations and between-group estimates are reproduced in Table 2; they have not been recalculated from participant-level data.

Time point	PRP mean $\pm$ SD	Hylan mean $\pm$ SD	Mean difference (95% CI)	Reported p-value
Baseline	7.1 $\pm$ 0.9	7.0 $\pm$ 0.8	0.1 (−0.2 to 0.4)	0.54

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1 month	5.9 ± 0.9	5.8 ± 0.9	0.1 (−0.2 to 0.4)	0.61
2 months	5.1 ± 0.8	5.2 ± 0.9	−0.1 (−0.4 to 0.2)	0.57
4 months	3.8 ± 0.8	4.5 ± 0.9	−0.7 (−1.0 to −0.4)	<0.001
5 months	3.4 ± 0.8	4.3 ± 0.9	−0.9 (−1.2 to −0.6)	<0.001
6 months	3.1 ± 0.7	4.2 ± 0.9	−1.1 (−1.4 to −0.8)	<0.001
9 months	3.3 ± 0.8	4.5 ± 1.0	−1.2 (−1.5 to −0.9)	<0.001

Table 2. VAS outcomes as reported. Negative mean differences favour PRP because lower scores indicate less pain. Confidence intervals and p-values require verification against the original analysis output.

WOMAC outcomes

The supplied manuscript reports a baseline mean WOMAC score of 58.4 ± 8.1 in the PRP group and 57.9 ± 8.4 in the hylan G-F 20 group. Scores were reported to decrease in both groups. The reported results are shown in Table 3 and have not been recalculated.

Time point	PRP mean ± SD	Hylan mean ± SD	Mean difference (95% CI)	Reported p-value
Baseline	58.4 ± 8.1	57.9 ± 8.4	0.5 (−2.5 to 3.5)	0.74
1 month	50.7 ± 7.8	50.9 ± 7.9	−0.2 (−3.0 to 2.6)	0.89
2 months	45.1 ± 7.2	46.0 ± 7.5	−0.9 (−3.6 to 1.8)	0.51
4 months	37.2 ± 6.8	42.9 ± 7.1	−5.7 (−8.2 to −3.2)	<0.001
5 months	33.8 ± 6.4	41.0 ± 7.0	−7.2 (−9.6 to −4.8)	<0.001
6 months	31.2 ± 6.1	40.2 ± 7.1	−9.0 (−11.4 to −6.6)	<0.001
9 months	32.6 ± 6.3	42.1 ± 7.4	−9.5 (−12.0 to −7.0)	<0.001

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Table 3. WOMAC outcomes as reported. Negative mean differences favour PRP because lower scores indicate fewer symptoms. The WOMAC version, score range and scoring method should be specified from the original study documents.

Subgroup findings

The supplied manuscript describes effects in the same direction in men and women and in both radiological grades. It reports that statistical significance was reached from month 6 in the BMI 18.6–25 kg/m² category and from month 5 in the BMI >25 kg/m² category. No subgroup estimates, confidence intervals, sample sizes or interaction tests were available. Differences in the time point at which a p-value crossed a significance threshold do not demonstrate that BMI modifies treatment effect. These analyses should remain explicitly exploratory and should not support subgroup-specific treatment recommendations.

Adverse events

Adverse events were not systematically recorded in the information available for this revision. The frequency, type, severity and relatedness of adverse events therefore cannot be reported, and safety cannot be assessed reliably. This absence of systematic reporting must not be interpreted as evidence that no adverse events occurred.

Discussion

In the supplied summary results, both treatment regimens were associated with lower reported VAS and WOMAC scores during follow-up. Between-group estimates favoured the three-dose PRP regimen from month 4 onwards. At month 6, the reported between-group differences were -1.1 points for VAS and -9.0 points for WOMAC. These estimates are descriptive summaries from the supplied manuscript and require verification against the original dataset and statistical output.

The central interpretive limitation is that the interventions differed in both product and injection schedule: PRP was administered three times, whereas hylan G-F 20 was administered once. The observed differences therefore compare two treatment regimens

and cannot establish that PRP itself is biologically superior to hylan G-F 20. The design also cannot distinguish a delayed or cumulative effect of repeated PRP from waning benefit after a single hylan injection, or from a combination of these explanations. Previous comparative trials and meta-analyses have reported heterogeneous results for PRP and HA-based treatments [12–21]. Differences in PRP preparation, injection number, comparator formulation, disease severity and outcome timing limit direct comparisons across studies. The current manuscript does not adequately characterise the PRP preparation, so its results cannot be generalised confidently to other PRP products or protocols. The proposed biological mechanisms of PRP were not assessed through biomarkers, synovial-fluid analysis or structural imaging in this study and remain hypotheses rather than findings.

The reported subgroup findings are insufficient to identify patient groups that benefit more. Subgroup sample sizes and interaction estimates were not available, and a difference in the first time point with a nominally significant result is not a valid test of effect modification. The analyses should be considered hypothesis-generating only.

Several reporting and design limitations affect interpretation. The randomisation sequence and allocation concealment were not documented in the supplied material, and blinding could not be confirmed. These omissions prevent readers from assessing selection, performance and measurement bias. No a priori sample-size calculation was performed. The analysis used separate comparisons at multiple time points without modelling within-participant correlation or adjusting for multiplicity; reported p-values may consequently overstate the strength of evidence. Since source data were unavailable, no reanalysis could be undertaken. The

absence of systematic adverse-event records prevents reliable safety assessment. Participant follow-up, ethics approval details and data availability also require verification. The reported outcomes are patient-reported symptoms and function only. No structural or disease-modifying outcome was measured, and the findings should not be interpreted as evidence that either intervention slows OA progression or regenerates cartilage. Generalisability is limited to the reported population with grade II–III disease in a single centre and cannot be extended to grade IV OA.

Strengths reported in the supplied manuscript include a comparative parallel-group design, reporting of two patient-reported outcomes, and planned follow-up to nine months. However, the inability to verify the underlying dataset and study records limits the confidence that can be placed in the reported estimates. Before publication, the authors should retrieve the source records if possible, verify participant flow and all tabulated results, clarify the interventions and eligibility criteria, and seek independent statistical review. If records remain unavailable, this limitation must be disclosed explicitly.

Future studies should be prospectively registered, use a justified sample-size calculation, document sequence generation and allocation concealment, characterise PRP composition, prespecify a primary outcome and time point, standardise or document co-interventions, systematically collect harms, and use an analysis plan that accounts for repeated measurements and multiplicity. Comparisons with matched injection schedules would help distinguish the effects of product from injection frequency.

Limitations

The study report has important limitations. First, three PRP injections were compared with one hylan G-F 20 injection, preventing attribution of differences to the product alone. Second, no a priori sample-size calculation was performed. Third, the randomisation sequence, allocation concealment and implementation procedures are undocumented in the supplied material.

Fourth, blinding, co-interventions and treatment adherence could not be verified. Fifth, PRP preparation details and radiographic grading criteria are incomplete. Sixth, adverse events were not systematically recorded, so safety cannot be assessed reliably. Seventh, separate time-point tests did not account for repeated measurements or multiple comparisons. Eighth, subgroup estimates and interaction tests are unavailable. Ninth, participant flow and complete follow-up could not be independently verified. Tenth, the ethics approval number was unavailable and the trial was not registered. Finally, the original dataset and statistical output were unavailable for independent verification or reanalysis. These limitations should be resolved where possible before submission; otherwise they should remain explicit in the published report.

Conclusion

The summary results supplied for this manuscript indicate improvement in pain and function in both groups, with lower reported VAS and WOMAC scores in the three-dose PRP group than in the single-dose hylan G-F 20 group from approximately month 4. Because the intervention schedules differed, this is a comparison of regimens and does not establish the biological superiority of PRP. The original dataset and methodological records were unavailable for verification, adverse events were not systematically recorded, and follow-up completeness could not be independently confirmed. The reported findings should therefore be interpreted cautiously and verified before submission.

Declarations

Funding: The supplied manuscript states that no funding was received.

Ethics approval and consent to participate: The supplied manuscript states that the study was approved by the hospital ethics committee and that written informed consent was obtained. The approval number and supporting documentation were unavailable for this revision and require author verification.

Trial registration: The supplied manuscript states that the trial was not registered in a public registry.

Conflicts of interest: The supplied manuscript states that no conflicts of interest were declared. All authors should reconfirm this statement.

Data availability: The supplied manuscript states that datasets are available from the corresponding author on reasonable request. This statement could not be verified because the original dataset was not available for this revision. It must be changed to accurately reflect whether the data exist, can be accessed, and can be shared.

Author contributions: Not provided in the supplied manuscript. Add an accurate contribution statement agreed by all authors if required by the target journal.

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