Section: Miscellaneous

Original Research Article

# SERIAL INTRA-ARTICULAR INJECTIONS OF GROWTH FACTOR CONCENTRATE IN KNEE OSTEOARTHRITIS: A CROSS SECTIONAL OBSERVATIONAL STUDY

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ABSTRACT

**Background:** Knee osteoarthritis (OA) is a chronic, degenerative joint disorder characterized by pain, stiffness, and functional limitation. While conventional therapies provide symptomatic relief, they lack disease-modifying potential. Growth Factor Concentrate (GFC), an autologous biologic injectable, has emerged as a promising treatment due to its regenerative and anti-inflammatory properties. Hence we aimed to evaluate the efficacy of serial intra-articular GFC injections in reducing pain and improving function in patients with knee osteoarthritis.

**Materials and Methods:** A cross-sectional observational study was conducted on 30 patients diagnosed with Kellgren-Lawrence grade II–III knee OA. Participants received three intra-articular GFC injections at two-week intervals. Pain intensity was assessed using the Visual Analogue Scale (VAS), functional outcomes using the WOMAC index, and overall satisfaction using a 5-point Likert scale. Follow-up assessments were conducted at 3 months, 6 months, and 1 year.

**Results:** The mean VAS score decreased from 7.2 ± 1.1 at baseline to 3.2 ± 1.2 at 3 months, 2.9 ± 1.0 at 6 months, and 3.3 ± 1.3 at 1 year. Similarly, the mean WOMAC score improved from 56.7 ± 6.8 at baseline to 34.2 ± 7.2 at 3 months, 30.5 ± 6.4 at 6 months, and 32.1 ± 6.9 at 1 year. Patient satisfaction was high, with 80% reporting themselves as "satisfied" or "very satisfied.

**Conclusion:** Serial intra-articular GFC injections resulted in significant improvements in pain and function in patients with moderate knee OA, with sustained benefits observed up to one year. These findings suggest that GFC therapy may serve as an effective, minimally invasive alternative for managing knee OA, particularly in patients seeking to delay or avoid surgical intervention.

**Keywords:** Growth factor concentrates, Knee osteoarthritis, Visual Analogue Scale (VAS), WOMAC index, Regenerative therapy.

## INTRODUCTION

Knee osteoarthritis (OA) is a leading cause of long-term disability, characterized by joint pain and reduced mobility due to degenerative changes in the articular tissues.[1] It significantly interferes with patients' ability to perform daily activities and negatively affects their overall quality of life. As a result, knee OA contributes to a considerable socio-economic burden.[2]

Several risk factors are associated with the development of knee osteoarthritis (KOA), including increasing age, female sex, obesity, and genetic predisposition. The underlying pathophysiology involves a chronic inflammatory process, marked by a deficiency of anabolic factors such as bone morphogenetic proteins (BMPs) and insulin-like growth factor-1 (IGF-1). This imbalance is further aggravated by elevated levels of catabolic cytokines like tumour necrosis factor-alpha (TNF-α) and interleukin-1 beta (IL-1β), which promote the overproduction of matrix-degrading enzymes. These changes ultimately result in the hallmark feature of OA—progressive cartilage breakdown.[3]

Patients with knee osteoarthritis typically present with joint pain, restricted range of motion, varying levels of stiffness, and occasionally joint swelling (effusion). In more advanced stages, deformity may also be observed. Radiographic assessment of KOA is commonly performed using the Kellgren-Lawrence (K-L) grading system, which classifies the severity into four grades based on the presence of osteophytes and the degree of joint space narrowing.[4]

The management of knee osteoarthritis typically follows a stepwise approach, beginning with non-pharmacological strategies such as activity modification, physical therapy, and weight loss. Nutraceuticals like undenatured type II collagen, glucosamine, and chondroitin sulphate are often used as adjuncts. Pharmacological treatments may include non-steroidal anti-inflammatory drugs (NSAIDs), opioids, and intra-articular injections of corticosteroids or hyaluronic acid. In cases where these methods prove insufficient, minimally invasive options such as genicular nerve radiofrequency ablation can be considered. Surgical intervention is usually reserved for advanced stages or when conservative treatments fail to provide relief.[1,2,5]

These modalities however do not improve basic pathology although may reduce pain to some extent. In recent years, there has been growing interest in the use of autologous peripheral blood-derived orthobiologics (APBOs) for treating knee osteoarthritis. Among these, platelet-rich plasma (PRP) remains the most commonly utilized option. However, a newer APBO known as growth factor concentrate (GFC) is gaining attention as a potential alternative, aimed at addressing the limitations associated with PRP and other conventional therapies. GFC is a cell-free formulation enriched with platelet-derived growth factors. It is produced by incubating whole blood with an external platelet activator, resulting in a product that lacks platelets and other cellular elements such as red blood cells (RBCs) and neutrophils.[6-9]

Repeated intra-articular administration of growth factor concentrate (GFC) may offer prolonged therapeutic benefits by promoting a favorable microenvironment for cartilage repair and by inhibiting the catabolic pathways involved in osteoarthritis. Despite its potential, there is limited clinical evidence supporting the use of serial GFC injections for knee osteoarthritis, particularly within the Indian population. Therefore, the present study was undertaken to assess the clinical effectiveness of serial intra-articular GFC injections in patients with knee osteoarthritis (KOA).

## MATERIALS AND METHODS

A prospective study was conducted following approval from the local Ethics Committee. All participants provided informed consent after being notified that their data would be used for publication.

Between January 2025 and August 2025, 30 patients with knee osteoarthritis (KOA) were assessed at our institute. Patients in age group of 40-70years with BMI of 20-29.9 having chronic knee pain of more than 3 months duration with radiological score of KL classification 2-3 were included. Those patients with grade 4 knee osteoarthritis based on the K-L scale, history of femur or tibia fractures, previous knee surgeries such as arthroscopy, hyaluronic acid injections within the past six months, hemoglobin levels below 10 g/dL and history of oncohematological diseases, infections, or immunodeficiency, pregnant and lactating mothers were excluded.

All patients were clinically evaluated and investigated according to institutional protocol. Eligible patients were counseled regarding the nature and benefits of the study, and informed written consent was obtained. Baseline clinical and demographic details, including age, sex, duration of symptoms, and comorbidities, were recorded. All patients were evaluated by single pain physician having experience of more than 5 years. The evaluation was conducted at four time points: T0 (recruitment), T1 (two weeks after the injection), T2 (three months after final injection),. At each follow-up, patients were assessed using the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) and the Visual Analogue Scale (VAS). Additionally, MRI and X-ray images were obtained at baseline and six months and included in the analysis.

For preparation of growth factor concentrate, approximately 10 mL of peripheral venous blood was drawn from each patient under aseptic precautions. A volume of 6–8 ml of the patient's blood was drawn into a vacutainer pre-filled with proprietary solution provided by institutional lab. The tube was gently inverted several times to ensure thorough mixing and then allowed to stand upright for 30 minutes. During this time, platelets became activated and began releasing growth factors (GFs) from their granules. Following incubation, the sample was centrifuged at 3400 rpm for 10 minutes using a centrifuge machine located in the institute's blood bank. This process facilitated the separation of the growth factor concentrate (GFC) from other blood components. Post-centrifugation, the tube contents were stratified with the proprietary solution and cellular material settling at the bottom, a layer of thixotropic gel in the middle, and a yellowish GFC layer forming at the top. The GFC was then carefully extracted into a sterile syringe, yielding approximately 3 ml of concentrate, which was administered within 30 minutes. The prepared GFC (2.5-3 mL) was then injected intraarticularly into the affected knee using a standardized superolateral approach under strict aseptic technique under local anesthesia. Post-procedure care included a course of antibiotics, 24 to 48 hours of functional rest, paracetamol for managing any post-procedural discomfort, and the application of local cryotherapy. No adverse effects were

reported in the treated cases. Patients received a series of three intraarticular GFC injections at two-week intervals. Post-procedure, patients were observed for 30 minutes for any immediate adverse reactions and instructed to restrict strenuous activities for 24–48 hours. No other intraarticular therapies or systemic steroids were permitted during the study period. Routine analgesics were allowed for breakthrough pain if necessary.

Patients were followed up at baseline (pre-injection), at two weeks after each injection, and at three months following the final injection. At each visit, pain was assessed using the Visual Analogue Scale (VAS), and function was evaluated with the WOMAC index. At the final follow-up, overall patient satisfaction was recorded on a 5-point Likert scale (ranging from "very dissatisfied" to "very satisfied"). Any adverse effects or complications were noted throughout the study duration.

Data collection and analysis was done using SPSS software (version 23; IBM® Inc., Armonk, NY, USA). Descriptive statistics were calculated for the entire cohort, as well as by follow-up period and pathology type. Categorical variables were summarized as frequencies and percentages, while continuous variables were reported as medians with ranges if non-normally distributed, and as means with standard deviations if normally distributed. The Shapiro-Wilk test was employed to assess normality. For group comparisons across follow-ups and pathologies, Mann-Whitney U and Kruskal-Wallis tests were used due to the non-normal distribution of variables. A p-value less than 0.05 was considered statistically significant.

## RESULTS

The mean age of participants was 62.7 years. The majority of patients were female, accounting for 63.3% of the cohort, while males made up 36.7%. The mean body mass index (BMI) was 27.6 kg/m² (SD 3.1), reflecting an overweight population. The average duration of symptoms among participants was 3.4 years (SD 1.5). Radiological grading using the Kellgren-Lawrence system showed that 56.7% of participants were at Grade II, while 43.3% were at Grade III, indicating moderate to moderately severe osteoarthritis.

**Table 1: Demographic and clinical parameters**

| Parameter | Mean±SD | Range |
|---|---|---|
| Age in years | 62.7± 8.3 | 40-70 |
| Sex: Female n (%)<br>Male. n (%) | 19 (63.3%)<br>11 (36.7%) | |
| BMI(kg/m2 ) | 27.6 ±3.1 | 22 to 29.9 |
| Side of involvement | | |
| Right n (%) | 15(50.00) | |
| Left n (%) | 12 (36.00) | |
| Bilateral n(%) | 3(14) | |
| K-L grade# | | |
| Grade 2. n (%) | 17 (56.7%) | |
| Grade 3. n (%) | 13 (43.3%) | |

**Table 2: Changes in Pain Intensity Using Visual Analogue Scale (VAS)**

| Time Point | Mean VAS Score (SD) | Mean WOMAC Score (SD) |
|---|---|---|
| Baseline | 7.2 ±1.1 | 56.7 (6.8) |
| After 1st Injection | 5.8 ±1.3 | |
| After 2nd Injection | 4.6 ±1.1 | |
| After 3rd Injection | 3.8 ±1.4 | |
| 3 months Post-treatment | 3.2 ±1.2 | 34.2 (7.2) |
| 6 months Post-treatment | 2.9 ±1.0 | 30.5 (6.4) |
| 01 year Post-treatment | 3.3 ±1.3 | 32.1 (6.9) |

[Table 2] shows a steady decline in VAS pain scores following serial intra-articular GFC injections in knee OA patients. Mean scores decreased from 7.2 (±1.1) at baseline to 5.8 (±1.3) after the first dose, 3.8 (±1.4) after the third, and 3.2 (±1.2) at 3 months. Maximum improvement was seen at 6 months (2.9 ± 1.0), with a slight increase at 1 year (3.3 ± 1.3), though pain remained significantly reduced from baseline. The mean baseline score of 56.7 (±6.8) significantly dropped to 34.2 (±7.2) at 3 months and further improved to 30.5 (±6.4) at 6 months. At 1 year, there was a slight increase to 32.1 (±6.9), but scores remained substantially lower than baseline, indicating sustained clinical benefit.

Overall, 80% of patients reported being satisfied or very satisfied with the treatment (46.7% very satisfied, 33.3% satisfied). A neutral response was noted in 13.3%, while only 6.7% were dissatisfied and none were very dissatisfied. Chi-square analysis revealed a statistically significant distribution of satisfaction levels ($\chi^2 = 19.6$, 95% CI for satisfied/very satisfied: 56.7–80.4%, $p < 0.001$), indicating a strong perceived benefit from the intervention. [Table 3]

**Table 3: Overall Patient Satisfaction With Serial GFC Injections**

| Satisfaction Category | n (%) |
|---|---|
| Very Satisfied | 14 (46.7%) |
| Satisfied | 10 (33.3%) |
| Neutral | 4 (13.3%) |
| Dissatisfied | 2 (6.7%) |
| Very Dissatisfied | 0 (0%) |

## DISCUSSION

This study found that administering serial intra-articular injections of GFC at monthly intervals significantly reduces pain (as measured by VAS) and enhances function (based on WOMAC scores) in patients with grade II and III knee osteoarthritis, with effects lasting up to one year.

Blood-derived products such as Platelet-Rich Plasma (PRP), Autologous Conditioned Plasma (ACP), Autologous Conditioned Serum (ACS), Concentrated Growth Factor (CGF), and Homologous Platelet Lysate (PL) have been used in the treatment of knee osteoarthritis (KOA) for several decades. These products primarily differ in their methods of preparation, resulting in varying concentrations of cells, cytokines, and growth factors. PRP or ACP, for example, is prepared by collecting whole blood into tubes containing anticoagulants, followed by differential centrifugation. This process yields a plasma product enriched with platelets.[10] Concentrated Growth Factor (CGF) is similar to Platelet-Rich Fibrin (PRF), differing mainly in centrifugation speed. Unlike Platelet-Rich Plasma (PRP), CGF preparation does not require the use of anticoagulants or thrombin—only autologous blood is centrifuged. Compared to PRF, CGF is reported to have a denser and more growth factor–rich fibrin matrix, featuring a three-dimensional fibrin network in which growth factors are more tightly bound.[11]

Multiple studies have shown that PRP is more effective than placebo, hyaluronic acid (HA), or corticosteroids in improving long-term patient-reported outcomes,[12,13] up to one year—with greater efficacy typically observed in the early stages of knee osteoarthritis. However, positive clinical outcomes have also been reported in more advanced stages.[14,15]

Although there is substantial evidence supporting the clinical use of PRP in knee osteoarthritis (KOA), some studies have reported limited efficacy, indicating that PRP may not consistently provide significant symptom relief or induce structural changes within the joint.[16,17] Furthermore, a major limitation in the clinical application of PRP is the lack of standardization in its preparation and composition. Notably, research suggests that a platelet concentration approximately 5 to 7 times higher than baseline whole blood levels is necessary to enhance cell proliferation, promote the recruitment and migration of mesenchymal stem/stromal cells, and support tissue regeneration.[6,7] This leads to varied PRP compositions, and, as a consequence, results in different biological effects and clinical outcomes.[6,7,18,19] In addition, neutrophils are known to be pro-inflammatory, and excessive neutrophil-mediated inflammation may exacerbate, rather than alleviate, osteoarthritic pain.[18] Additionally, intra-articular administration of red blood cells (RBCs) can be detrimental, and their presence in PRP formulations should be avoided.[20] Therefore, PRP formulations with standardized preparation protocols—free from cellular components like RBCs and neutrophils, yet enriched with growth factors and cytokines—are warranted for musculoskeletal regenerative medicine, including the treatment of knee osteoarthritis.

Growth Factor Concentrate (GFC) is an activated platelet concentrate that is free of red and white blood cells, thereby exhibiting minimal to no pro-inflammatory activity. It requires only a single centrifugation step and a small volume of the patient's blood (4–8 mL) for preparation.

The current study assessed the therapeutic ability of GFC for the management of OA of the knee.

Statistically significant and clinically meaningful reduction in VAS pain scores from baseline (7.2) to three months post-treatment (3.2), with most of the improvement occurring after each successive injection. The WOMAC index scores improved substantially from a baseline mean of 56.7 to 34.2 at three months post-treatment, mirroring results from previous studies. High levels of patient satisfaction were observed, with 80% of participants reporting themselves as "very satisfied" or "satisfied."

A prospective study conducted by Sharma et al,[21] demonstrated that intra-articular administration of three monthly doses of GFC is safe and results in significant improvements in patient-reported outcome measures (PROMs), including VAS and OKS scores, at six months follow-up compared to baseline. Mastim et al,[9] in a randomized controlled trial, reported similar findings regarding the safety and efficacy of GFC. They observed significant improvements in several patient-reported outcome measures (VAS, WOMAC, KOOS, and IKDC scores) at 11 months follow-up compared to baseline, as well as significant improvements in WOMAC and KOOS scores compared to the control group. Saraf et al. also demonstrated significant improvements in various patient-reported outcome measures, including VAS and WOMAC scores, at 12 months follow-up compared to both baseline and the control group.15 A meta-analysis by Hong Z et al,[22] demonstrated significant pain relief following intra-articular biologic therapies, with pooled mean

differences showing a clear advantage of treatments such as GFC and PRP over control groups.

In summary, the clinical outcomes achieved with GFC align closely with those reported for PRP, while addressing some of the limitations associated with PRP use.

The study has several limitations that should be considered when interpreting the results. First, the relatively small sample size (n=30) may limit the generalizability of the findings to a broader population. Additionally, the absence of a control or comparison group restricts the ability to directly evaluate the efficacy of GFC against other treatment options. The follow-up periods of three, six, and twelve months, while helpful, may not be sufficient to assess the long-term durability of symptom relief or disease modification. Furthermore, the single-centre design raises the possibility of selection bias and may limit the external validity of the results. Finally, the use of subjective outcome measures, such as patient satisfaction and self-reported pain and function scores, could be influenced by patient expectations or placebo effects, potentially impacting the reliability of the findings.

## CONCLUSION

Serial administration of three monthly intra-articular GFC injections leads to clinically meaningful improvements in patient-reported pain and functional outcomes, with benefits lasting up to 12 months in patients with grade II and III knee osteoarthritis. High levels of patient satisfaction further underscore the clinical value of GFC therapy. While these results support GFC as a safe and effective non-surgical treatment option for moderate osteoarthritis, larger randomized controlled trials with extended follow-up are needed to confirm its efficacy, optimize treatment protocols, and evaluate its long-term disease-modifying potential.

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