"A PROSPECTIVE COMPARATIVE STUDY OF FLUOROSCOPIC GUIDED SINGLE INTRA-ARTICULAR INJECTION OF AUTOLOGOUS PLATELET RICH PLASMA VERSUS CORTICOSTEROID IN DEGENERATIVE FACET JOINT SYNDROME – A RANDOMISED CONTROL TRIAL"

BY
DR. ARYADEV JAYAKRISHNAN, MBBS



DISSERTATION SUBMITTED TO SRI DEVARAJ URS ACADEMY OF HIGHER EDUCATION AND RESEARCH, KOLAR, KARNATAKA

In partial fulfilment of the requirements for the degree of

MASTER OF SURGERY
IN
ORTHOPAEDICS

Under the Guidance of
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PLATELET RICH PLASMA VERBUS CONTICOSTERIOR IN
DESCENERATIVE FACET JOINT SYNDROME - A PANDOMISED
CONTROL TRIM.

Background

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A PROSPECTIVE COMPARATIVE STUDY OF
FLUOROSCOPIC GUIDED SINGLE INTRAARTICULAR INJECTION OF AUTOLOGOUS
PLATELET RICH PLASMA VERSUS
CORTICOSTEROID IN DEGENERATIVE FACET JOINT
SYNDROME – A RANDOMISED CONTROL TRIAL



ABSTRACT

Background

Lumbar facet joint (LFJ) therapies are beneficial for detection and management of persistent low back pain (LBP), including degenerative facet joint syndrome (DFJS). These procedures require intra-articular (IA) injections of drugs using various techniques. IA facet joint (FJ) injection has been demonstrated to be effectual in the management of facetogenic pain in previous researches. The direct administration of steroids into the joint has been shown to have a variety of adverse effects. Platelet-rich plasma (PRP) is advantageous because of its cost-effectiveness, autologous properties, minimal invasiveness, and ease of acquisition and preparation. Consequently, PRP does not show the negative side effects that are commonly associated with other frequently used medications.

Aim and Objective

To analyse the functional outcome of a single injection of autologous IA PRP compared to single injection of IA corticosteroid (CS). This study strived to analyse the short-term and long-term effectiveness of both treatments in the management of DFJS.

Methodology

All consecutive patients who were diagnosed with DFJS between September 2022 and May 2023 and were admitted to the Orthopaedics department at R.L. Jalappa hospital, Kolar. A computer online random generator software was used to randomly allot the sample of 74 cases into two groups, with 37 in each group. Group A patients received IA PRP injection, while patients in Group B received IA CS injection. Patients were monitored at 4 weeks, 8 weeks, 12 weeks, 6 months and 1 year after receiving an IA injection. During the follow-up, each patient was evaluated using several assessment tools, including the Visual Analog Scale (VAS), Present Pain Index (PPI), Modified Oswestry low back pain Disability Index (MODI), Roland-Morris Questionnaire (RMQ), and Short Form Health Score-12 (SF-12).

Results

There is a significant decrease in pain in both the groups. PRP is better than steroid in reducing perceived pain, improving disability and quality of life (QOL) in the long term (1 year). Steroid is better than PRP in reducing perceived pain, improving disability and QOL at short term, though not found to be statistically significant (1 month to 6 months).

Conclusion

An ideal new injectable medicine for treating DFJS is autologous PRP. Both PRP and steroid injections were easy, effective, and safe enough to use for treating LFJ conditions after one year of follow-up. Both groups saw a substantial reduction in pain and impairment, which was assessed using the VAS, MODI, RMQ, and PPI questionnaires. Both groups saw a notable enhancement in their health-related QOL, as assessed by SF-12 scores. However, when considering therapeutic options, autologous PRP may provide a better choice due to its longer-lasting effectiveness.

Keywords: Intra-Articular Corticosteroid Injection, Intra-Articular PRP Injection, Degenerative Facet Joint Syndrome, Visual Analogue Scale, Modified Oswestry Disability Index, Present Pain Index, Roland-Morris Questionnaire Score, Short Form Health-12 Score

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ABBREVIATIONS

Sl#	Abbreviation	Explanation
1	AP	Articular Pillar
2	BMC	Bone Marrow Concentrate
3	CS	Corticosteroid
4	COX-2	Cyclo-Oxygenase-2 inhibitors
5	CFS	Cervical Facet Syndrome
6	DFJS	Degenerative Facet Joint Syndrome
7	DDD	Degenerative Disc Disease
8	FA	Facet Arthritis
9	FJ	Facet Joint
10	FJP	Facet Joint Pain
11	FJS	Facet Joint Syndrome
12	GBCAs	Gadolinium Based Contrast Agents
13	GF	Growth Factor
14	GAGs	Glycosaminoglycans
15	НА	Hyaluronic Acid
16	IAP	Inferior Articular Process
17	IA	Intra-Articular
18	IVD	Intervertebral Disc
19	LFJ	Lumbar Facet Joint
20	LBP	Low Back Pain
21	LA	Local Anesthesia
22	MBDR	Medial Branch of Dorsal Rami
23	MBB	Medial Branch Block
24	MODI	Modified Oswestry Low Back Pain Disability Index
25	NSAIDS	Non-Steroidal Anti-Inflammatory Drugs
26	OA	OsteoArthritis
27	PPI	Present Pain Index
28	PRP	Platelet Rich Plasma
29	PLC	Posterior Ligamentous Complex
30	QOL	Quality Of Life
31	RA	Rheumatoid Arthritis
32	RMQ	Roland-Morris Disability Questionnaire
33	RPM	Revolutions Per Minute
34	SF 12	Short Form Health Score-12
35	SPECT	Single-Photon Emission Computed Tomography
36	SAP	Superior Articular Process
37	VAS	Visual Analogue Scale
38	VB	Vertebral Body

INTRODUCTION

Impairment and exorbitant medical expenses are consequences of the epidemic of back pain that is sweeping the globe.¹ At least 40% of the population will have low back pain (LBP) during their lives, and this condition has far-reaching consequences for both individuals and society as a whole.²

Facet joints (FJ) are among the several spinal structures that can cause LBP. Degeneration, inflammation, and repetitive trauma increases the risk of facet joint pain (FJP), which manifests as pain on moving the affected joint, and it primarily affects the elderly.³

When the inferior articular process (IAP) of a vertebra meets the superior articular process (SAP) of the lower vertebra, a FJ is formed. Load transmission and bearing, spinal stabilization during flexion and extension, and restriction of excessive rotation are all responsibilities of the FJ.⁴

Degenerative facet joint syndrome (DFJS) is a medical disorder that causes erosions in the cartilage, diminishes joint space, and thickening of the subchondral bone. There are a number of factors that contribute to an increased risk, including age, sagittal alignment of the FJ, and concomitant degeneration of the intervertebral disc (IVD).⁴ Degeneration, a progressive disorder, can

occur because of changes in the biochemical and structural properties of several tissues leading to alteration in the mechanical properties of the joint. The mechanical behaviour of the entire segment of spinal motion is affected, as they are interdependent with the IVD in their mechanical function. Degeneration is a result of damage, infection, aging, and inflammatory disorders like septic arthritis, synovitis, and rheumatoid arthritis (RA). It is defined by the breakdown of tissues at a structural and cellular level.⁵

Patients arrive with persistent, unprovoked LBP. Typical patterns include LBP that is confined and exhibits a non-dermatomal radiation pattern. Seldom felt below the knee, pain from the lumbar spine usually refers to the area of the buttock and thigh. Weakness and numbness in lower extremities is highly unlikely however nerve root irritation can cause lumbar radiculopathy in cases with osteophytes, large synovial cysts, or facet hypertrophy.⁴

Facet degeneration pain can be efficiently treated utilizing a variety of techniques, including spinal manipulation, physical therapy, medication, radiofrequency lesioning, facet blocks, and surgery. These techniques are all effective in treating the pain. In addition to physical therapy, the restoration of correct body mechanics and teaching correct standing postures are also essential components of the treatment process. It is essential to build the abdominal muscles as well as the deep flexor muscles in the neck to achieve a balance between the excessive activity of the extensor muscles in the back and neck.

Oral pain medications, such as steroids, nonsteroidal anti-inflammatory drugs (NSAIDs), or cyclo-oxygenase-2 inhibitors (COX-2), might be recommended as the first line of treatment for those who are experiencing acute facet arthritis (FA) pain or quick exacerbations of chronic FA pain. Spinal manipulation can be performed using either the muscle energy technique or the high-velocity low-amplitude procedure. Both techniques are methods that can be utilized to realign the FJs and alleviate discomfort.

Facet blocks and medial branch blocks (MBB) are two procedures that can help ease the pain of FA. Ultrasound, landmarks, or fluoroscopic guidance can all be used to direct these procedures. As a first line of treatment, surgery is usually not suggested for the management of FA. When multiple issues, such as severe spinal stenosis or ruptured discs, lead to intolerable pain, motor function loss, or incontinence, surgery may be considered as a potential treatment option.⁶

Interventions involving the lumbar FJ (LFJ) are helpful in the diagnosis and treatment of long-term LBP. There are a variety of approaches to treating discogenic LBP, as Raj et al. and Simon et al. thoroughly examined.^{7,8} Surgical methods like fusion and disc replacement are the focus of treatment because it is often assumed that deteriorated discs cause discogenic pain. Since these surgical techniques reportedly only provide pain relief, their reliability and efficacy are still up for question.⁹ As a replacement, non-invasive modalities have been

practiced to address discogenic pain, including physical therapy, benign neglect, and symptom control with injections or medication. Although these therapies alleviate the symptoms of the underlying degenerative condition, they do little to improve the problem itself. ¹⁰ Some of the side effects of injecting steroids into an affected joint include hyperglycaemia, high blood pressure, gastrointestinal issues, worsening of heart failure, dizziness, and urticaria. This strongly suggests that novel treatments are required to address the root causes of discogenic pain. So, new methods including growth factor (GF) therapy, biomolecular treatments, and cellular treatments have been getting a lot of focus.

Platelet-rich plasma (PRP) is autologous blood that has higher platelet agglomeration than whole blood. It is produced by separating the liquid and solid constituents of blood using a centrifugation technique. PRP injections show promise in assisting disc tissue regeneration and repair. There have been a few of case studies that have suggested PRP injection as a secure means to manage degenerative disc disease (DDD) in patients whose LBP has not responded to conventional treatments. One of these is the work of Lutz and colleagues. Percutaneous injection of PRP promotes tissue regeneration in musculoskeletal disorders. A number of orthopaedic conditions, including hamstring injuries, achilles tendinopathy, lateral epicondylitis, rotator cuff tears, knee osteoarthritis (OA), and ulnar collateral ligament tears, have shown improvement after receiving PRP injections. 14

PRP comes with the benefits of being easy to prepare and produce, minimally invasive, and made from the patient's own blood. As a result, PRP does not have the side effects seen with other drugs. Many doctors now offer PRP injections to their patients as an alternative to hyaluronic acid (HA) and corticosteroid (CS), two of the most common intra-articular (IA) injectants.¹⁵

With this background knowledge on FJ interventions, including intraarticular FJ steroid injections, MBB, and radiation denervation of the medial branch nerves, that are often carried out in clinical settings, this study sought to weigh up the impact of IA injections of PRP and CS in improving the functional outcome in DFJS.

NEED FOR THE STUDY

A great deal of debate exists over the safety, effectiveness, and therapeutic impact of platelet-rich plasma (PRP) compared to corticosteroid (CS) injections in degenerative facet joint syndrome (DFJS). The current study aimed to analyse the functional outcome of single dose of autologous intra-articular (IA) PRP injection compared to single dose of IA CS injection. The study also aimed to evaluate the short-term and long-term effects of both treatments in the management of DFJS.

OBJECTIVES

- 1. To evaluate the functional result of an autologous platelet rich plasma (PRP) injection given intra-articularly (IA) in patients with degenerative facet joint syndrome (DFJS).
- 2. To evaluate the functional result of single IA corticosteroid (CS) injection in DFJS.
- 3. To compare the functional outcome of a single IA autologous PRP injection versus CS injection in DFJS.

REVIEW OF LITERATURE

Anatomy of Facet joint

The exclusive synovial joints found in the spine are FJs, which are also known as zygapophyseal joints in historical literature. The posterior arch is articulated postero-laterally between adjacent vertebral levels by means of these coupled diarthrodial joints. The main stabilizers of the spinal column, the LFJs allow for motions such as extension, flexion, and rotation.¹⁶



Figure 1: Axial CT image of LFJ.83

The FJs make up the articular pillars that give the vertebral column its structural integrity. They are located between the vertebral pedicle and lamina. The lower vertebra's superior facet articulates with the inferior facet of the preceding vertebra. ¹⁷

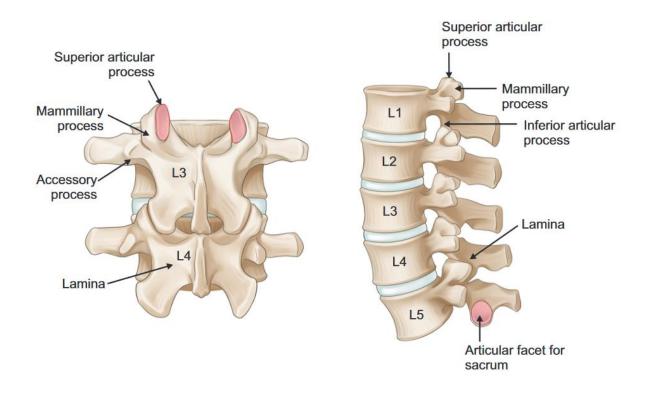


Figure 2: Images depicting the back and side views of the lumbar vertebrae and its FJs.³

In each vertebral arch, bony projections known as SAP and IAP protrude vertically from the junction where pedicles intersect laminae. They are located on the same side, behind the transverse process. Above the subchondral bone, articular hyaline cartilage covers the surfaces of the SAP and IAP. As the

hyaline cartilage does not have any blood vessels or cells infiltrating it, it does not heal very well after an injury.

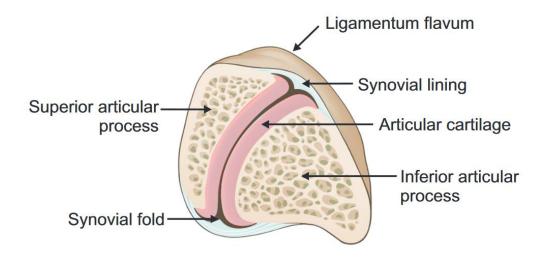


Figure 3: A cross-sectional view of the LFJ.³

Anatomically, the LFJ cavity can be divided into two distinct areas: the articular space of the LFJ and the recesses of the FJ. It is the actual physical distance between the cartilage of the articulating facets that is referred to as the FJ gap.¹⁶

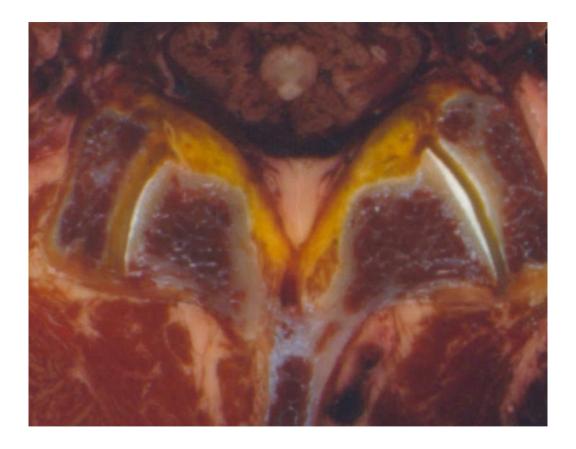


Figure 4: Transverse section of the FJ at L2/3 level.86

The LFJ is encased by a capsular ligament at the top and bottom of the joint, which results in the formation of FJ recesses that may contain adipose tissue or tiny synovial villi. LFJ cavity have no direct link with the retro-dural region and have a distinct anatomical boundary. LFJ recesses and cavities can be seen using MRI during radiologic examination. The joint space capacity is believed to be around 1-2 mL. The property of the property

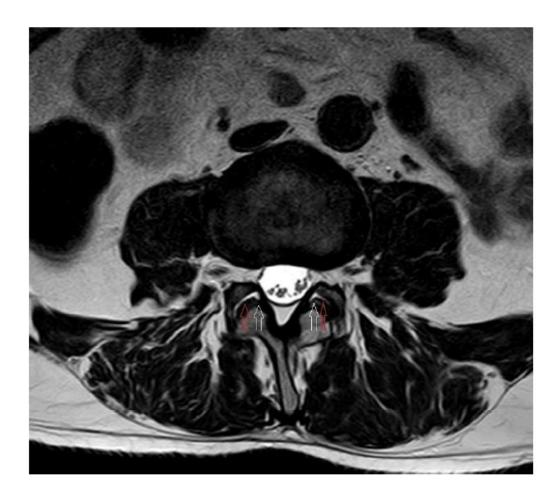


Figure 5: Axial section MRI of a normal L3-L4 FJ depicting FJ cavity (red arrow) and anteromedial superior recess (white arrow)¹⁶

The capsular ligament has two layers when viewed under a microscope. One layer is made up of tightly arranged collagen bundles that run parallel to the lateral-medial direction. The second layer consists of elastic fibres that have an uneven orientation. Furthermore, the capsular ligament has a complex network of autonomic and nociceptive nerve fibres that can produce pain sensations resulting from mechanical or inflammatory stimulation.¹⁶

The synovium, the subchondral bone, and the capsule of the FJs are innervated by nerve fibres that are both nociceptive and autonomic in nature.¹⁸ There have been reports of substance P nerve fibres being discovered in subchondral bone in patients with DDD.¹⁹ The initial description of the three branches that originate from the spinal nerve and extend throughout the dorsal muscles was provided by Bogduk et al. (Fig. 6).²⁰

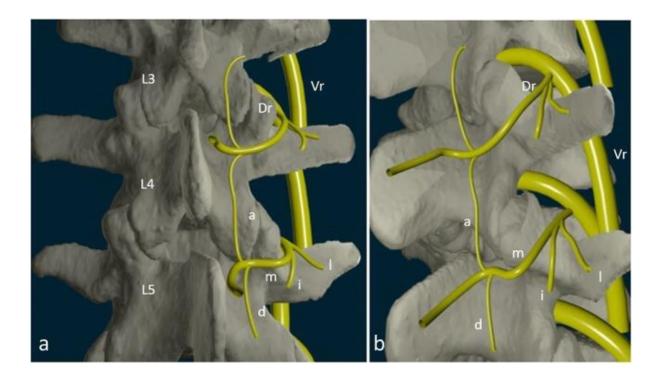


Figure 6: The provision of nerves to the FJs at the levels of L3–L4 and L4–L5. Vr: The ventral ramus. Dr: Dorsal ramus. m: Medial branch. i: Intermediate branch. l: Lateral branch. a: Ascending branch. The "d" represents the descending branch. View of the back (a) and back and side (b) of the lower part of the spine.²¹

Innervation of every LFJ between L1 and L4 is provided by the medial branch of the dorsal rami (MBDR). When performing denervation of the FJ, it is essential to take into consideration the one-of-a-kind branch distribution of the L5 segment. The root of SAP of sacrum intersects with ala to form the furrow through which the L5 dorsal ramus passes. This dorsal ramus is longer than those at higher levels. The course is comprised of two different branches: an intermediate branch and a medial branch. It is characterised by the absence of a lateral branch.²⁰



Figure 7: Dorsal view of left L5 dorsal ramus. Ilium resection showed the ramus as it crossed the ala of the sacrum. zJ, zygapophysial joint; I, ilium; SI, S1 dorsal foramen and ramus; dr, L5 dorsal ramus; ib, intermediate branch; mb, medial branch.²⁰

Biomechanics of Lumbar Facet Joint

Being the sole synovial joints in the spine, FJs can be engaged in a variety of functions. The motion unit, also called the functional unit of the spine is formed by two adjacent vertebral bodies (VB), an IVD and two FJs.¹⁷

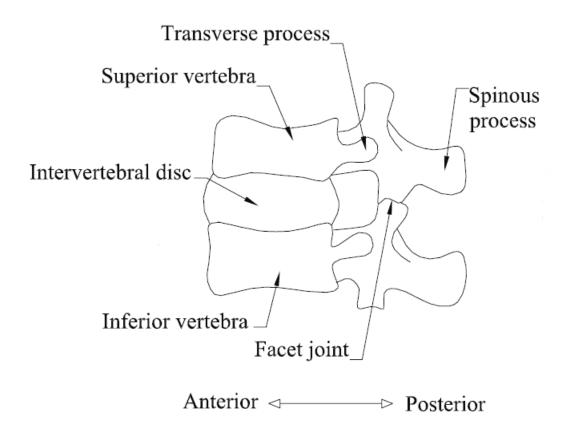


Figure 8: Schematic representation of the motion segment.²²

The lumbar articular facets are sagittal oblique oriented, which minimizes rotation, while the thoracic FJs are coronally oriented, which minimizes extension but enables rotation. The posterior component of the spinal motion segment, which governs spinal mobility, the type of motion is determined by the plane of facet articulation. The back of the motion segment contains a vital supporting element known as the posterior ligamentous complex (PLC). PLC

consists of the ligamentum flavum, articular facet capsules, supraspinous ligament, and interspinous ligament.¹⁷

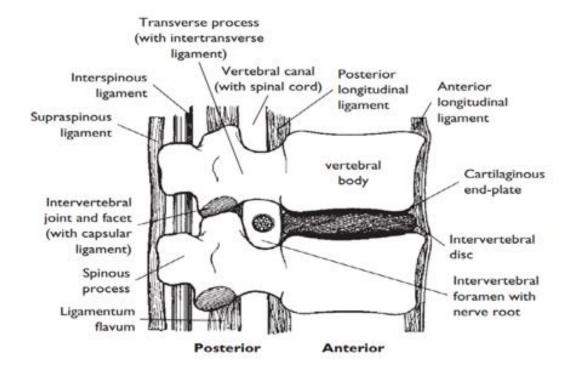


Figure 9: Schematic representation of the PLC, the motion segment and different columns of a vertebra.²³

The FJs directly influence the spine's stress response due to their mechanical nature, anatomical orientation, and proximity to the IVD. There are two FJs located postero-laterally to each motion segment at every level, from cervical to the lumbar spines. The posterolateral regions of the spine consist of the paired FJs, and their positioning is symmetrical in relation to the mid-sagittal plane.⁵

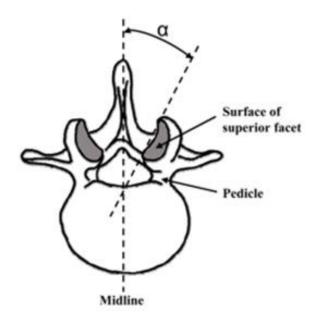


Figure 10: Axial orientation of a LFJ.⁵

The primary elements of a FJ consist of the articular pillars (AP), which are coated in cartilage, the synovium and a capsule that encloses the whole joint. During rotational and translational movements, the capsular ligament resists tensile pressures while the articular pillars sustain compressive loads.

APs are bony projections running along the whole length of the spine, originating from the lamina on both sides. In thoracic and lumbar locations, they connect to the VB through bony pedicles. In the lumbar area, the APs are completely enclosed by the laminae which enables stress to spread from the upper to lower articular facets through the lamina.⁵

Compared to cervical and thoracic regions, the lumbar area has a more convex superior facet of the lower vertebra. The more concave inferior facet on

the vertebra above, curves rearward towards the VB, forming the opposite side of the spine. The upper lumbar spine is composed of approximately 80% curved FJs and 20% flat FJs. The numerals are reversed in the lower lumbar spine.²⁴

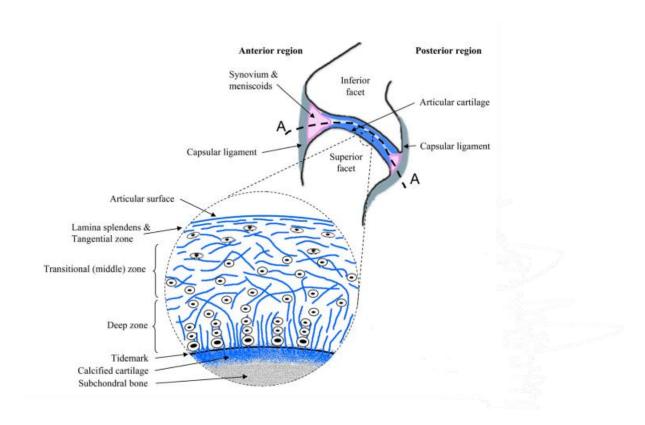


Figure 11: Diagrammatic image of the FJ and the layers of the articular cartilage. A cut section of the FJ (A-A) reveals the cartilage surface and the elliptically-shaped IA surfaces.⁵

Multiple layers of cartilage on the articulating surfaces allows smooth movement between the neighbouring vertebrae, while simultaneously providing support for compressive, tensile, and shear forces. The mechanical property of cartilage is attributed to its unique structure and the composition of the matrix. GAGs (glycosaminoglycans), proteoglycans, chondrocytes, and collagen fibers

make up the cartilage matrix. The presence of collagen and elastin provides significant resistance against shear and tensile pressures that occur during movement and when the spine is under strain. The capsular ligament has a significant biomechanical function in the varied motion of LFJ and is elongated during lateral flexion or rotation. Therefore, the capsular fibres are oriented in a lateral-medial direction and extend along the path of the LFJs, contributing to functional resistance and stability.¹⁶

Averting possible strain and injury to the surrounding structures, like IVD, nerve roots exiting the spinal column, and the spinal cord, the LFJs prevent relative movements between adjacent vertebrae. Mechanical stress is thus transmitted onto the FJ tissues. Yang and King state that between seventy-five and ninety-seven percent of the compressive force acting on the lower back is transmitted via the IVD. They postulated that 3-25% of the load is carried by the posterior elements and dubbed it as "facet force".⁵

Low back pain (LBP)

Society bears a tremendous financial and emotional weight due to this prevalent pain disease. Several factors contribute to the high expenses of health care, such as incorrect diagnoses, excessive use of imaging, unnecessary surgeries, and work stoppages.²⁵

Particularly in the elderly, LBP limits mobility and makes it hard to carry out routine, everyday activities.²⁶ According to reports, LBP costs a total of 48.960

billion euros annually in Germany, making it the most costly condition in developed nations.²⁷ In USA, the incidence of LBP has been reported to range anywhere from fifteen percent to forty-five percent, according to a cross-sectional study.²⁸ The incidence of FJ OA is highest at the L4-S1 levels in India. It affects a significant proportion, ranging from 89% to 95%, of those aged 65 and above.²⁹

In addition to the FJs, IVD, sacroiliac joints, and nerve roots may be causes of LBP and can be assessed using imaging and other diagnostic method. The use of imaging alone might be challenging when it comes to identifying discogenic low back pain, LFJ discomfort, and sacroiliac joint pain in the absence of a disc herniation.²⁵

History

- In 1911, Goldthwait was the first to note their potential influence as a source of LBP.³
- Ghormley initially suggested the name "facet syndrome" in 1933. It was
 formerly used to characterize sciatica-related pain that could or might not
 accompany lumbosacral discomfort.³⁰
- Eventually, Badgley suggested that, regardless of whether the spinal nerve was compressed or not, FJs could be the primary cause of pain. For the purpose of demonstrating the involvement of FJ in LBP, a large

number of individuals experiencing LBP who did not have herniated discs were assessed.³¹

- In 1963, Hirsch et al. laid out the basic physiological theory that supports FJP. Injecting hypertonic saline into the area around the FJs relieved patients pain.³²
- By injecting a hypertonic saline solution into the FJs of asymptomatic volunteers under fluoroscopy guidance, McCall et al. demonstrated the induction of back and lower extremity discomfort.³³

Degenerative Facet joint syndrome

Facet joint syndrome (FJS) is the term used to describe pain originating from one or more FJs. Alterations in the spinal joints that are caused by degenerative processes are the primary cause of this syndrome. The cartilage that lines the FJ can become damaged and inflamed, which can result in pain signals being transmitted to the nerve terminals that are located in the surrounding area.³⁴

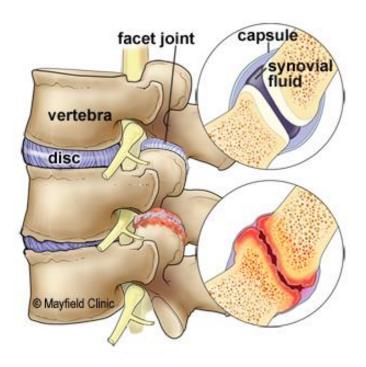


Figure 12: The lateral perspective of the spinal column reveals a typical IVD and FJ at the uppermost part. Arthritic pain, oedema, and stiffness at the bottom might result from wear and strain on the disc and FJ.³⁴

LFJs are frequently the cause of discomfort, often misinterpreted, mistreated, and treated incorrectly.²⁵ The majority of cases involving the FJs are due to OA.³⁵ It is currently not possible to establish a reliable connection between clinical symptoms and degenerative spinal alterations, even though imaging is often used to diagnose back pain syndrome. In addition, there are situations in which imaging data might not appear to be pertinent to the therapeutic scenario, which further contributes to the confusion.³⁶

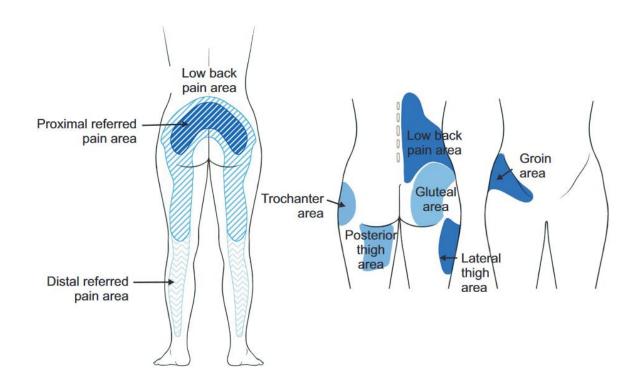


Figure 13: Visualization of the distribution pattern associated with FJ pain.³

It is possible to have soreness in either one or both sides in the back that proceeds down the leg, into the buttocks, groin, or the thighs, and finally ends just above the knee. This condition is referred to as clinical FJS.³⁷ When patients are experiencing LBP, it is possible that they may not always be able to differentiate between the discomfort caused by FJs and the discomfort caused by herniated discs or compressed roots. These days, a lot of clinical practice uses the pain referral patterns to diagnose LBP associated with FJP. In the context of treatment, Kaplan et al. demonstrated that the injection of local anaesthetics (LA) into the joints could potentially reduce the discomfort that is associated with FJP.³⁸

Etiology

Spondylosis, or spinal degeneration, is the leading cause of FJ dysfunction.

OA is a degenerative joint disease that develops because of wear, tear and aberrant body mechanics.³⁹

Although OA is a complex process involving the interaction of several cytokines and proteolytic enzymes, its pathophysiology is still not fully understood. Obesity, old age, gender, certain occupations, previous traumas or operations all have a part in the development of OA. FJ disease can also be caused by trauma resulting from an injury or sports activities. Inflammatory disorders such as RA and ankylosing spondylitis may potentially be influenced by synovial inflammation. Spondylolisthesis is another contributing factor to the development of FJ disease, as it results in the subluxation of the FJs. FJ disease can lead to pain in individuals due to cartilage loss and inflammation. Consequently, the body will undergo several physiological alterations due to this process. Possible manifestations include hypertrophy and thickening of ligaments, such as the ligamentum flavum. Osteophytes, also referred to as "bone spurs", are produced with formation of new bone in the vicinity of the joint. Hypo mineralization can lead to an increase in subchondral bone volume.40

Epidemiology

FJS is mostly caused by degeneration, which has a disproportionate impact on the elderly. There is no evidence to suggest that men are more susceptible to being affected than women. A potential risk factor for FJ OA is a previous history of engaging in strenuous lifting activities before the age of 20.²¹ Obesity likely has a role in the development of FJ dysfunction, as it is a significant factor in the occurrence of OA.

The FJs are commonly affected by OA, leading to degenerative spondylolisthesis, which typically occurs at the L4-L5 level. The primary aetiologies of spondylolisthesis in younger patients (aged 30-40) include congenital abnormalities, stress, or acute fractures.²¹ Whiplash injuries have a prevalence rate of cervical facet syndrome (CFS) and discomfort ranging from 29% to 60%, whereas trauma is often not a typical cause.⁴¹

Clinical Presentation^{42,43}

Injuries to the FJs typically manifest as a localized, one-sided backache, but in extreme cases, they can radiate down a whole limb. A clinical examination is required to determine the origin of the pain. When compared to articular cartilage and synovium, the joint capsule is the most probable source of pain. LBP that radiates to the groin might be commonly seen.

CFS includes following symptoms:

- Pain in the axial region of the neck, which is most frequently unilateral and rarely radiates beyond the shoulders.
- The presence of pain with movements of the neck.
- Cervical tenderness.
- Localized or sporadic radiating sensation of pain along the arm or fingers, shoulders, upper back.

LFS can be characterised by following symptoms:

- LBP with tenderness may be present.
- Localized soreness or stiffness that is in the lower back, adjacent to the spine.
- Discomfort, stiffness, or trouble with specific motions (straightening up or getting out of a chair) are all symptoms that may be experienced.
- Pain upon hyperextension.
- Discomfort that originates in the upper LFJs may radiate to the flank, hip, and upper outer thigh.
- Pain that originates from the lower LFJs can travel deep into the thigh, either laterally or posteriorly.

• Pain that radiates into the distal lateral leg and, in extremely rare cases, to the foot can be referred from FJs of the L4-S1 vertebrae.

Imaging Techniques⁴⁴

X ray Radiographs:

Lateral and antero-posterior radiographs can visualize FJs. However, the "Scottie dog" symbol in oblique view is considered the most effective when it comes to visualizing FJ. When viewed laterally, the skeletal structure of a Scottish Terrier resembles the following: transverse process represents nose, pedicle represents eyes, inferior articular facet corresponds to front legs, superior articular facet represents ears, and the pars-interarticularis represents the neck.

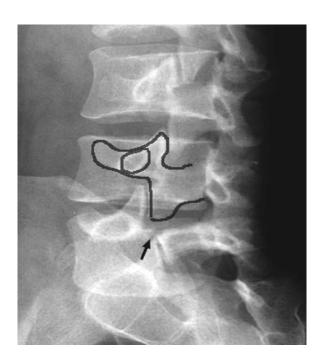


Figure 14: Plain radiograph of the lumbar spine representing "Scottie dog" sign. 82

CT scan:

CT is more effective than MRI in detecting bone pathology and provides a more detailed assessment of FJs. When it comes to spotting degenerative changes in FJs, CT scans outperform conventional radiography. Reason being contrast between hard and soft tissues can be better seen in CT images. Osteophytosis, erosions, subchondral sclerosis, and capsular calcification can be better seen using a CT scan. Changes in the soft tissues like hypertrophy of the ligamentum flavum and synovium. Due to the oblique nature of articular surfaces, a multi-planar analysis is necessary to examine their shape.

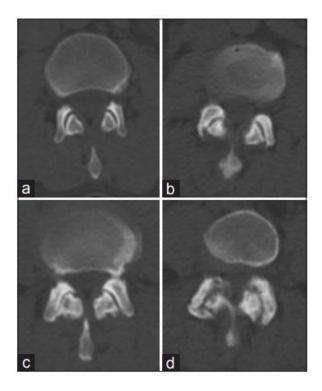


Figure 15: CT images of progression of FJ arthropathy showing narrowing joint space narrowing, osteophytes, hypertrophy, bony erosions and sub-chondral cysts.⁴⁵

MRI Scan:

MRI provides improved visualization of non-osseous changes such as oedema, synovitis, periarticular cysts, and impingement on nearby neural structures due to its high-resolution imaging of soft tissues. Up to 41% of individuals with back discomfort may develop subchondral bone oedema, a condition that can be detected using fat-suppressed MRI sequences. Gadolinium-based contrast agents (GBCAs) improve the accuracy and precision of MRI, facilitating the detection of alterations in the FJs and the structures around them.

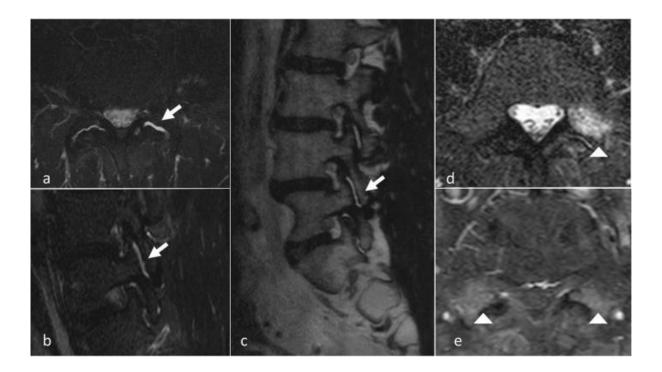


Figure 16: MRI of the FJs. There is inflammation in the synovial tissue and swelling within the joint.²¹

Others

By exposing increased uptake, which is a nonspecific signal, single-photon emission computed tomography (SPECT) imaging can provide extra information on inflammation in FJs. This includes the ability to provide new information. Through the utilization of hybrid techniques, PET/CT and PET/MRI can attain higher levels of accuracy in the diagnosis of a wide variety of pathological disorders when compared to the utilization of structural imaging alone.

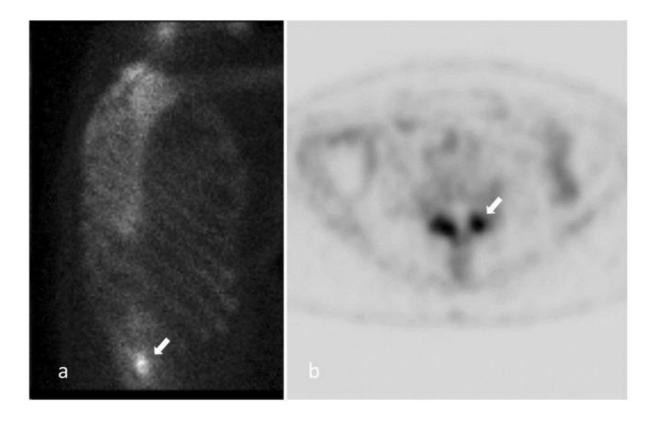


Figure 17: SPECT imaging of FJ. The user is hyper-focused on bone scintigraphy, specifically on the inflammation of the FJ capsule, shown by the white arrow.²¹

Diagnostic facet joint block injection tests⁴⁶

Administering a LA along with CS into the suspected FJ is a frequently used diagnostic procedure. If the discomfort subsides after the injection is administered with anaesthesia, it can be inferred that the pain originates from the FJ. Fluoroscopy, a real-time x-ray imaging technology, is used to direct diagnostic injections into the selected FJ. Contrast dye is commonly used to improve the imaging of joints and to prevent the inadvertent transfer of medicine into a blood vessel, known as vascular uptake.

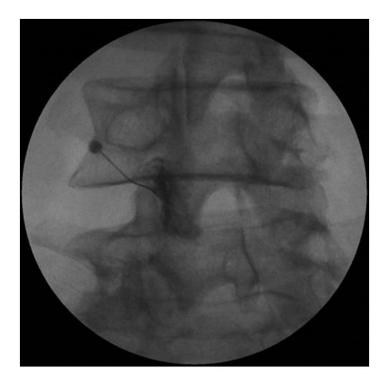


Figure 18: CS injection into the LFJ. Performing a fluoroscopy-guided injection of contrast into the FJ located between the left L4 and L5 vertebrae using a C-arm.⁴⁷

There is a risk of false-positive results from FJ block injections, even if they can accurately diagnose facet-based discomfort. A double-block strategy may be used to avoid false positive results. In a double-block method, the targeted joint is injected with a second block of LA (such bupivacaine or lidocaine) that have variable durations of action. Patients must have pain relief of at least 80% for the prescribed duration with each anaesthetic drug for the test to be considered positive.

Differential Diagnosis³⁹

- Hip OA localises to groin/buttocks, aggravates on squatting, sitting cross legged
- Sacroiliac impingement detected by FABER test, sacroiliac joint compression and distraction test
- Lumbar radiculopathy/Disc pathologies Radiating pain to leg/foot,
 straight leg raise test positive
- 4. Myofascial pain syndrome examination reveals trigger points on involved muscle
- 5. Compression fractures history of trauma, ruled out radiologically
- **6.** RA multiple joint pain, relieves with activity

Management 48

The therapy of FJS has significantly advanced during the past many years. Typically, the initial strategy to combat OA of the LFJs involves the use of anti-inflammatory and analgesic medicines.

IA injections of medications can alleviate pain by assisting in FJ healing or by functioning as an anti-inflammatory or analgesic. An alternative approach involves the potential to anesthetize or sever the nerves that innervate the FJs, so obstructing the transmission of pain signals. Various therapy approaches have advantages and disadvantages, and the ongoing discussion about their usefulness persists. Table 1 presents a concise overview of the attributes of various treatment methods.

Types of Treatment	Characteristics
MBB	Anesthetize the nerves innervating LFJ by local anesthetics to achieve short-term pain relief. It is often used in the diagnosis of facet joint syndrome.
Steroid Injections	Intra-articular injections are usually a mixture of steroid and local anesthetics. Pain relief is shorter than with radiofrequency ablation.
Medial Branch Radiofrequency Ablation	Medial branch radiofrequency ablation is a mainstream minimally invasive procedure for facet joint syndrome. However, some patients may have variation of medial branch anatomy, and a few patients have no pain relief after radiofrequency ablation.
Capsule Radiofrequency	Percutaneous radiofrequency to the LFJ capsule is easier than medial branch radiofrequency, and capsule radiofrequency leads to an extended period of pain relief compared to the medial branch radiofrequency.

Cryoneurolysis Using a gas-cooled cryoprobe to freeze the nerve with an

ice-cold temperature.

Chemical Neurolysis Nerve damage with chemicals. Nerve regeneration is

potentially dangerous to the formation of neuroma. It is

rarely used.

Dorsal Root Neurotomy Dorsal root neurotomy maintained significant relief of pain,

longer than medial branch denervation. But there are few

related studies.

Endoscopic Neurotomy Endoscopic neurotomy can directly observe the nerve.

Avoids the inconvenience of anatomical variation.

Endoscopic neurotomy is more effective than percutaneous

radiofrequency.

Table 1: Distinctive Attributes of Various Therapies for FJS.⁴⁸

Platelet rich plasma (PRP)

The procedure of centrifuging blood results in the production of autologous PRP. The PRP includes high concentrations of cytokines and GFs, which have the potential to stimulate cell proliferation, vascularization, cellular development, tissue regeneration, and collagen synthesis. Generally, these concentrations are anywhere from one to twenty-five times higher than what is observed in whole blood. 49 Table 2 presents the final product, which is a plasma platelet hyper concentrate. This hyper concentrate is classified into four primary categories according to the cellular composition of its fibrin structure. Injections of PRP have the potential to be beneficial in managing a variety of musculoskeletal conditions, including OA, hamstring injuries, and DDD etc. 50

Table 2: Classification of PRP Solutions.⁵¹

Classification	Description
Pure platelet-rich plasma (P-PRP)	Platelets only in a low-density fibrin network
Leukocyte and platelet-rich plasma (L-PRP)	Leukocytes and platelets in a low-density fibrin network
Leukocyte and platelet-rich fibrin (L-PRF)	Leukocytes and platelets in a high-density fibrin network
Pure platelet-rich fibrin (P-PRF)	Platelets only in a high-density fibrin network

Platelets are essential for the process of haemostasis, which involves blood clotting. Additionally, platelets possess properties that contribute to the regeneration of tissues. These include several biomolecules that exhibit biological functions, such as GFs, cytokines, and anti-inflammatory chemicals. The primary role of these substances is to stimulate various cells involved in the process of regeneration. Platelets promote the migration of cells such as fibroblasts, endothelial cells, and myogenic precursors to the wounded site, where they contribute to tissue regeneration.

Platelets include GFs, which are essential components that assist in the process of tissue regeneration. These include factors such as FGF, EGF, PLGF and others which assist in cell proliferation, differentiation, and extracellular matrix synthesis. GFs stimulate cellular pathways to enhance tissue regeneration. In addition to interleukins and TGF-β, PRP contains several additional biological components that possess anti-inflammatory characteristics. These substances facilitate tissue regeneration and regulate the inflammatory response.⁵²

In an RCT involving 82 participants with grade II and III knee OA, Kumar et al. used a double-blinded design. One set of subjects got CS injected IA, while the other group got PRP injected IA.⁴⁹ Longer period of pain relief was achieved in the PRP group. After a notable decline at the three- and six-month marks, the pain score showed a gradual ascent at the six-month mark. But in the CS group, it was still better than the values before the intervention. After three months of the intervention, all indicators of the WOMAC Scores had improved. In a three-month trial, the PRP group outperformed the CS group. After comparing PRP injections to CS, they found that the latter significantly improved short-term functional capacity and quality of life (QOL) while the former reduced joint pain for a longer duration and alleviated symptoms.

PRP injections in degenerative spine disease

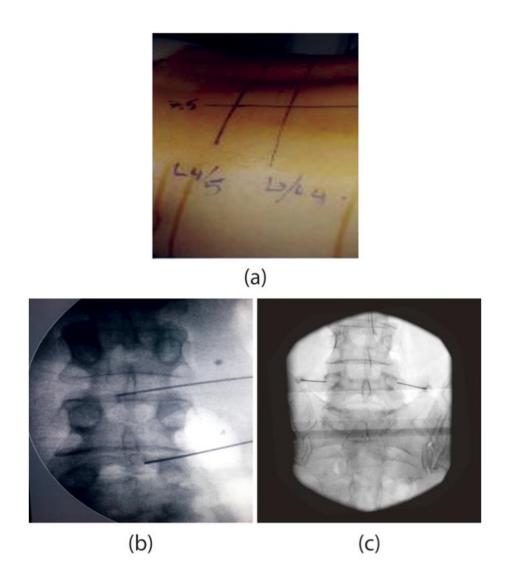


Figure 19: Here are two examples of PRP injections in individuals with DDD and FJS. After correctly positioning and covering the areas of interest, a paramedian method is used (a). Needle inserted using continuous fluoroscopy at the areas where PRP injections are administered. The image shows the injection of PRP into the IVDs at the L3-L5 levels (b), as well as into the articular facets of L4/L5 on both sides (c) during surgery.⁵¹

In a 6-month follow-up research, over half of the 22 patients with evidence of DDD in the lower lumbar spine showed improvement in their condition after receiving a single injection of autologous PRP.⁵³ While under observation, a few patients had a deterioration in their symptoms, however no significant adverse effects were observed.

A recent meta-analysis of research on PRP for lumbar DDD revealed a significant improvement in patients' QOL, as evaluated by the visual analogue scale (VAS).⁵⁴ Based on only two instances of temporary paraesthesia lasting fewer than seven days, the authors assert that the technique is both safe and potentially beneficial.⁵⁵

In order to determine if intradiscal PRP injection was effective in treating discogenic LBP, Chang and Park conducted a meta-analysis.⁵⁶ The ultimate analysis included an RCT and two prospective observational studies after the systematic review. Significant decrease in VAS scores at 2 & 6 months after intradiscal injection of PRP was noted, but no change at 1 month, based on the examination of changes in VAS scores. Over the course of six months, Oswestry disability index (ODI) scores dropped significantly. Intradiscal PRP injections effectively reduce pain and improve functional limits caused by discogenic LBP, according to their research. The injections' analgesic effects, however, won't be noticeable for at least two to six months after the first injection.

Navani et al in an RCT 2023, evaluated the safety and efficacy of Orthobiologic Injections for Discogenic Chronic LBP. They compared bone marrow and PRP injections to a placebo in treating chronic LBP. Pain and function were both significantly improved by bone marrow concentrate (BMC) and PRP. When compared to a placebo, the researchers found that PRP and BMC both improved pain alleviation and functional capacity. Still, other questions can't be answered without more large-scale randomized clinical trials.⁵⁷

In 2023, Kawabata et al performed a systematic study on the advancements in PRP treatment for spinal diseases. The researchers examined trials that assessed the role of PRP in healing IVD degradation, facilitating bone fusion in spinal surgeries, and assisting in the neurological recovery of individuals with spinal cord injuries. The study also examined studies that investigate the clinical uses of PRP in the treatment of DDD. These studies looked at the pain-relieving effects of PRP in LBP and radicular pain, as well as its ability to speed up bone healing following spinal fusion surgery. Preliminary research has demonstrated the encouraging ability of PRP to regenerate tissue, and clinical investigations have documented the safety and impact of PRP therapy in the treatment of several spinal conditions.⁵⁸

Steroid injections

Most of the research on FJ injection has focused on long-acting CS, which can decrease swelling and inflammation, inhibit the immune system, and interfere with neuronal communication in the C fibres. Injections of LAs are also usual.⁴³ Intra-articular, peri-articular, and medial branch injections can all penetrate FJ. Since inflammatory mediators are present in and around degenerative FJs, steroid injections should offer short- to medium-term pain relief. However, the efficacy of steroids in alleviating pain in FJs is still controversial in the scientific community.⁴³ Although historically, FJ pain has been diagnosed by injecting steroids into the joint, either intra- or peri-articularly, a study by Lilius et al. showed there were no significant changes in the results between the two.⁵⁹ The use of IA steroids to treat persistent LBP is discouraged by European guidelines.⁶⁰

Complications from facet joint injections

Only a small number of individuals encounter complications following injections into LFJs; these complications typically involve problems with the injection procedure or the medications used.⁶¹ Among these include meningitis, edema, septic arthritis, hematoma, excessive bleeding, irritation of the nerve roots, vasovagal responses, rupture of the facet capsule, psoas abscess, dural puncture, and discomfort.



Figure 20: Abnormal leakage of contrast into the epidural space during a FJ injection.³

An investigation, which involved over 43,000 FJ injections, revealed that just 4% of cases demonstrated intravascular penetration and 1.2% exhibited local hematoma. In addition, a mere 1% of patients encountered adverse symptoms such as vasovagal reactions, excessive bleeding, discomfort, or irritation of the nerve roots.⁶² The most common side effects seen were local swelling, stiffness at the needle site, and LBP. These side effects were brief and self-limiting in nature.

Abnormal patterns of contrast flow can happen from time to time. FJ injections commonly cause epidural leakage in addition to intravascular penetration. Recent studies have linked epidural leakage to a ruptured capsule around the FJs.⁶³ The use of an epidural injection as a substitute method might be considered in these instances. In addition, doctors have to aware because injections into the FJs or the epidural space might cause motor weakness.

Relevant studies

Hellmich et al compared the impact of CS alone to CS in combination with Mepivacaine in managing LFJS under CT guidance. 157 patients were recruited and divided into three groups. Patients in all three groups showed improvement in stress and rest pain. However, a more prolonged period of pain relief was noticed in patients who either received dexamethasone alone or dexamethasone with LA. They came to the conclusion that CS either alone or in combination with a LA is an effective option with no complications for the therapy of LFJS.⁸⁵

Using 46 patients diagnosed with LFJ disease in China between 2012 and 2016, Wu et al. compared the outcomes of PRP injections with those of CS IA injections. Within Group A, a total of 23 patients received IA injections of autologous PRP with the use of fluoroscopy. Within Group B, a total of 23

patients received IA injections of a mixture containing lidocaine and betamethasone. These injections were administered under the guidance of fluoroscopy. During periods of rest or when bending, both groups experienced significant upswing in VAS, Roland-Morris Questionnaire (RMQ), and MODI scores compared to before treatment. Within group B, the subjective satisfaction rate, as measured by the modified MacNab criteria, was 80% after 1 month. However, the objective success rate decreased to 85% after 6 months. Subsequently, these values declined further to 50% and 20% respectively, after the initial month. Over time, the numbers for group A increased. The researchers determined that administering autologous PRP together with a mixture of LA and CS directly into the LFJS was a secure, efficient, and straightforward method for treating the ailment. However, for a more durable and lasting impact, autologous PRP is the preferred option.⁵⁰

A prospective clinical evaluation was conducted by Wu J et al in 2016 among 19 patients who were administered the IA autologous PRP successfully. LBP dramatically decreased during flexion and during rest one week after the injection. Nine patients had "good" or "excellent" results right after therapy, followed by 14 patients after a week, 15 patients after a month, 15 patients each after two & three months. Based on the ODI score, there was a greater than 10%

enhancement in functional capacity between the pre- and post-treatment periods, and statistically relevant improvements were noted in the RMQ.⁶⁸

Assessing 19 patients who received IA PRP injection, Liu et al. performed a prospective clinic evaluation. Following a week of treatment, there was a significant reduction in LBP both at rest and during flexion, in comparison to the pre-treatment condition. Out of the total number of patients, nine individuals (47.37%) achieved "good" or "excellent" outcomes immediately following therapy. This number increased to fourteen patients (73.68%) after one week, and further increased to fifteen patients (79.95%) after one month, two months, and three months. Significant improvements in lumbar functional capacity, exceeding a 10% increase, were observed. Additionally, there was a statistically significant improvement in RMQ scores during the pre- and post-treatment periods.⁶⁴

Hirase et al. conducted a comprehensive review to investigate the role of PRP intradiscal injections for treating lumbar DDD. Two sample Z-tests were used to compare the VAS scores of pains before and after injections. Five pieces of writing were examined. They concluded that intradiscal PRP injection for DDD improved VAS significantly with low rates of complications and re-

injection in this comprehensive study however further studies at a larger scale are required for a definitive assessment.⁵⁴

In a prospective RCT, 30 patients with LFJS were separated into two equal groups and given injections of PRP or CS, according to Kotb et al. Prior to and during the intervention, patients underwent evaluation using MRI LFJ synovitis grading, questionnaires assessing functional impairment due to LBP, and VAS score to measure the intensity of LBP. The researchers discovered that MRI-detected FJ synovitis showed improvement after both PRP and CS injections. Additionally, all evaluated parameters demonstrated improvement at the 3-month follow-up. However, PRP had more effectiveness in decreasing the severity of synovitis as assessed by MRI, suggesting that it may be a more appropriate option for treatment with prolonged effectiveness.²

Chandan Singh et al conducted a prospective study from 2017 to 2019 on comparing IA LFJ injection of PRP and CS in managing chronic LBP. Patients were randomised into groups: CS with radio-frequency ablation (RFA), PRP with RFA and RFA with normal saline as control group. Both PRP and CS injections were found to be safe and beneficial for treating LFJS after a 6-month follow-up. At three and six months, Group P's VAS decreased more than Group S's. Group P outperformed Group S in the MODI at six months, whereas Group

S outperformed Group P in the MODI at one month. They concluded that after 6 months both PRP and CS injections were determined to be efficient and risk-free for the treatment of LFJS, however PRP may be an improved option for longer duration.⁷⁶

David Kennedy et al in 2018 conducted a prospective placebo-controlled RCT on CS Injections into LFJs. Using fluoroscopic guidance, those with verified FJ pain by dual comparative MBB were randomized to receive either saline by injection or IA CS (triamcinolone 20 mg). They discovered that, in patients with FJ pain, dual comparative MBB confirmed that CS injections into the LFJs were ineffective in lowering the necessity for radiofrequency neurotomy of the medial branches.⁸⁴

Dong Gyu Kwak et al did retrospective research in 2019 on IA LFJ CS injection for FJ arthritis. 50 patients were recruited and pain intensity was evaluated using pain scale prior to treatment and at 1, 2 & 3 months after treatment. The findings showed that, irrespective of the degree of FJ OA, intra-articular LFJ CS injection dramatically decreased FJ origin LBP. They concluded that intra-articular LFJ CS injection is a beneficial option for managing FJP due to OA.⁷⁷

Jeremiah F. Ling et al conducted a systematic review in 2021 on PRP vs CS Injection for Lumbar Spondylosis and Sacroiliac Arthritis. Five studies were analysed. Four studies found that both modalities of treatment led to a statistically significant fall in VAS scores. At three- to six-month follow-up, three studies discovered that PRP patients had more notable improvements in their outcome ratings. At long-term follow-up, they drew the inference that while both injections are safe and effective choices, there is evidence to suggest that PRP injection is more beneficial.⁷⁸

Aakash Patel et al in his comprehensive review in 2022 on PRP in the Treatment of Facet Mediated LBP, systematically reviewed studies. Two of the studies that were analysed were retrospective, and one was prospective. The findings demonstrated that PRP is a viable substitute for traditional pharmaceutical treatments, interventional injections, and radio-ablation for facet-mediated pain. They came to the conclusion that well planned research is necessary to comprehend the effectiveness, adverse effects, and optimal methods.⁷⁹

Jayasoorya et al conducted a review in 2024 on PRP injections for LBP. Their study included a range of research on the use of PRP for transforaminal, intra-facet, and intradiscal injections. Autologous PRP injections have been shown in numerous studies to be a safe and effective conservative treatment option for LBP. They came to the conclusion that autologous PRP, because of its longer-lasting effectiveness, is a preferable treatment alternative.⁸⁰

MATERIALS AND METHODS

STUDY DESIGN:

A prospective open labelled comparative randomized control trial. Those patients who presented to the Department of Orthopaedics and Emergency Department at R.L Jalappa Hospital, a teaching hospital of Sri Devaraj Urs Academy of Higher Education and Research, Kolar and was diagnosed with DFJS were the subjects of the study after the inclusion criteria was met. Following admission patients were randomized into two groups by block randomization technique with block size of 4.

STUDY PERIOD AND DURATION

July 2022 to May 2023 (11 months)

SAMPLE SIZE:

74 (Group A 37 patients and Group B 37 patients)

Using the mean and standard deviation of the VAS score in the CS group at 104 weeks as 42.4 ± 268.8 and the mean and standard deviation of the VAS score in the PRP group at 104 weeks as 21.3 ± 28.1 at a 95% confidence interval with 90% power, the sample size is determined as follows, per the Gosens et al⁶⁵ study:

The formula used for calculation of sample size is:

$$N = (Z1-\alpha/2 + Z1-\beta)2 * 2 * \sigma 2/(\mu 1 - \mu 2)2$$

 $Z1-\alpha/2$ - two tailed probability for 95% confidence interval = 1.96

Z1-β - two tailed probability for 90% power = 1.28

 $\mu 1$ - mean of VAS score in corticosteroid group at 104 weeks = 42.4

 μ 2 - mean of VAS score in PRP group at 104 weeks = 21.3

 σ - Average standard deviation of VAS score in corticosteroid group at 104 weeks & VAS score in PRP group at 104 weeks = 27.45

$$N = (1.96 + 1.28)^2 * 2 * 27.45^2 / (42.4 - 21.3)^2$$

$$N = 35.57$$

Hence, minimum sample size required for each group is 36 and the total sample size is 74.

INCLUSION CRITERIA:

- Patients aged 35-80 years of either gender
- Persistent or intermittent LBP with or without referred pain to the buttock, groin, or lower limbs
- Features of LFJ degenerative changes on lumbar spine radio-imaging with the clinical symptoms and signs

 Patient with persistent pain irrespective of being treated with conservative treatment such as physical therapy, manipulation, and non-morphine treatment

EXCLUSION CRITERIA:

- Patients who had previous spine surgery
- Patients who received prior injection treatment in the past 3 months, such as nerve root injection
- Spinal tumors or tuberculosis
- Multi-level spinal deformity or spinal stenosis
- Not suitable for local injection
- Use of oral anticoagulants or history of drug abuse
- Infection, pregnancy, severe diabetes, allergic to the drug used in this study
- Associated heart disease, liver and kidney dysfunction, and hematological diseases
- Psychological and cognitive disorders

METHOD OF COLLECTION OF DATA:

Block randomization technique using a computer generator software was used for allotment of cases for both groups where Group A received single PRP dose and Group B received CS dose

In the group A patients who were randomized to receive PRP, 10ml of whole blood was collected in an EDTA vacutainer. Blood was initially centrifuged with a light spin at 2630 Revolutions per minute (RPM) for 3 minutes and 1500 RPM for another 15 minutes to sediment the RBCs and WBCs. This device separates the platelet-rich fraction from the patient's anticoagulated blood using a desktop centrifuge with disposable cylinders. PRP was transferred in the sterile container. 2ml of autologous PRP was then given as IA injection into the FJ to Group A cases.

Group B patients received CS. A mixture of 1ml of 4mg/ml Dexamethasone and 1ml of 0.5% of Lidocaine was given through intra-articular injection.

PROCEDURE:

Patient was positioned in prone position. The target segment was identified using fluoroscopy. The fluoroscope was positioned slightly oblique to visualise the silhouette of the FJs. Obliquity of up to 60 degrees may be necessary for the lower lumbar spine, whereas 30 degrees may be necessary for upper lumbar spine.

Following marking of entry point, LA was infiltrated into the skin and superficial muscles. Once the designated entry point was reached, a spinal needle of size 22-gauge 3½-inch, is introduced toward the joint along the fluoroscopy beam's axis until it makes contact with the joint's articular processes. To enter the joint space, some small manipulation could be required.

The needle is advanced by a few millimetres to penetrate the cavity of the FJ through the softer capsule, which was perceived as a mild change of resistance. After confirming the location of the needle tip, aspirate to rule out penetration of any vascular structure.

Once confirmed, a combination consisting of mixture of 1ml of 4mg/ml Dexamethasone and 1 ml of 0.5% of Lidocaine was injected into the FJ for patients in group B. Patients of group A received only 2 ml injection of autologous PRP into the FJ.

Following the procedure, the needle was removed, sterile dressing applied and the patients were shifted to recovery room.

FOLLOW UP VISITS:

Following intra-articular injection patients were assessed at 4 weeks, 8 weeks, 12 weeks, 6 months & 1 year. At the time of follow up each patient was assessed using VAS score, PPI score, MODI score, MRM score and SF-12 score.

STUDY VARIABLES

VAS score, PPI score, MODI score, RMQ score and SF-12 scores were considered as primary outcome variable. Treatment (CS/ PRP) was considered as primary explanatory variable. Age and gender were considered as the study relevant variables.

ETHICAL CONSIDERATION

The Institutional Ethics Committee granted its approval in terms of ethics (No.SDUMC/KLR/IEC/302/2022-23). The participants' privacy and secrecy were maintained throughout the study by only using the collected data for the intended purposes of the study.

Informed written consent was obtained from patients who were willing to participate in the study and undergo the procedure treatment.

Collection of data from 74 patients diagnosed with DFJS, within the age group of 35-80 years of either gender was taken up for the study.

DATA ANALYSIS

- The gathered data were imported into Microsoft Excel and then examined by IBM software for statistics SPSS 23.0. 81
- To characterize the data using descriptive statistics for discrete variables, frequency analysis and percentage analysis were used. The standard deviation, mean, and median were used for continuous variables.
- In order to characterize the data in inferential statistics, discrete variables
 in both groups were tested for statistically significant differences using
 either the Fisher's exact test or the Chi Square test. Using the Independent
 T test, continuous variables were examined for statistically significant
 difference.
- The probability value of 0.05 was regarded as the significant level in all the statistical techniques.

RESULTS

There is a significant decrease in pain in both the groups. PRP is better than steroid in reducing perceived pain, improving disability and quality of life (QOL) in the long term (1 year). Steroid is better than PRP in reducing perceived pain, improving disability and QOL at short term, though not found to be statistically significant (1 month to 6 months).

Table 3: Age variation comparison among the study groups

Age	PRP	Steroid
Mean	50.81	48.86
Median	53	48
Std. Deviation	7.774	10.773
Range	33	44
Minimum	28	34
Maximum	61	78

The mean age of the DFJS patients in PRP group was 50.81 ± 7.7 years and the mean of the DFJS cases in steroid group was 48.86 ± 10.7 years.

Table 4: Gender differences between the study groups compared

Gender	Pl	RP	oid	
	N	%	n	%
Female	16	43.2	19	51.4
Male	21	56.8	18	48.6
Total	37	100	37	100

About 56.8% of the DFJS patients were male in PRP group, and the remaining 43.2% were female. Similarly, 48.6% of the DFJS patients were male in steroid group, and the remaining 51.4% were female.

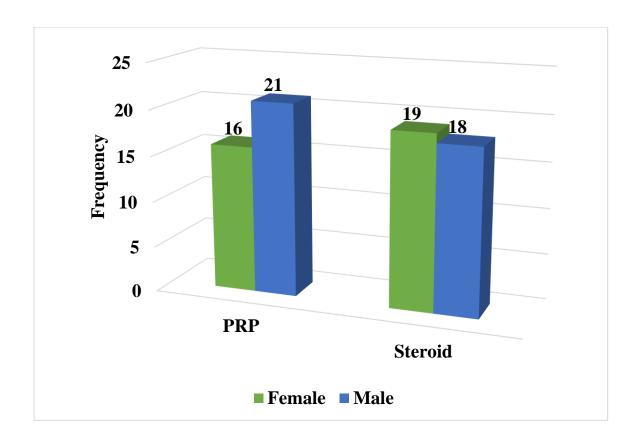


Figure 21: A multi-bar image illustrating the gender disparity among the study groups.

Table 5: Description of VAS score at different time of assessment in both the study groups

VAS	Baseline	4 Weeks	8 Weeks	12 Weeks	6 Month	1 Year				
PRP										
Mean	6.65	5.05	3.92	2.89	1.84	1.05				
Median	7	5	4	3	2	1				
S. D	0.676	0.575	0.493	0.516	0.501	0.229				
Range	3	2	2	2	2	1				
Min.	5	4	3	2	1	1				
Max.	8	6	5	4	3	2				
	1		Steroid							
Mean	6.76	4.35	3.27	2.32	1.3	2.65				
Median	7	4	3	2	1	3				
S. D	0.76	0.676	0.56	0.58	0.52	0.676				
Range	4	3	2	3	2	3				
Min.	5	3	2	1	1	1				
Max.	9	6	4	4	3	4				

The table above displays the mean VAS score that was measured at various time intervals before and after the PRP and steroid injection in the management of DFJS patients. The pain score was 6.65 prior to the PRP injection, but it

decreased to 5.05 after 4 weeks and to 3.92 at 8 weeks. Subsequently, the pain score declined at three months (2.89), further reduced at six months (1.84) and 1 year (1.05), all of which occurred after the PRP injection. In the treatment of DFJS patients, there is a consistent reduction in pain score after PRP injection.

The pain score was 6.76 prior to the steroid injection, but it decreased to 4.35 after 4 weeks and to 3.27 at 8 weeks. Subsequently, the pain score showed improvement at three months (2.32), with a significant decline at six months (1.3) and finally pain score increased at 1 year (2.65), all of which occurred after the steroid injection. In the treatment of DFJS patients, there is a consistent reduction in pain score after steroid injection.

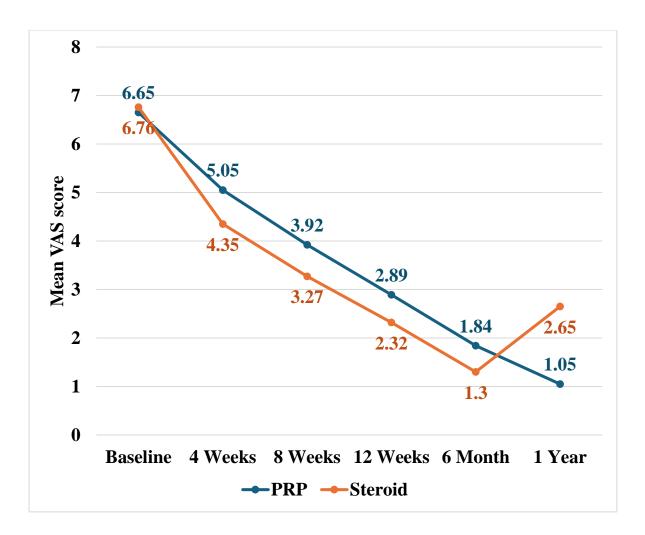


Figure 22: Line diagram showing mean VAS score at different time of assessment in both the study groups.

Table 6: Description of MODI score at different time of assessment in both the study groups.

Baseline	4 Weeks	8 Weeks	12 Weeks	6 Month	1 Year				
PRP									
54.97	50.14	44.49	38.38	29.92	21.19				
56	50	46	38	30	20				
4.634	4.703	5.342	6.052	6.282	5.915				
22	20	22	28	24	26				
46	40	30	20	16	10				
68	60	52	48	40	36				
		Steroid							
55.97	49.57	43.62	37.08	27.51	30.86				
56	48	42	36	26	30				
4.622	5.252	7.178	10.062	11.396	8.826				
22	24	36	54	62	50				
48	40	32	20	16	20				
70	64	68	74	78	70				
	54.97 56 4.634 22 46 68 55.97 56 4.622 22 48	54.97 50.14 56 50 4.634 4.703 22 20 46 40 68 60 55.97 49.57 56 48 4.622 5.252 22 24 48 40	PRP 54.97 50.14 44.49 56 50 46 4.634 4.703 5.342 22 20 22 46 40 30 68 60 52 Steroid 55.97 49.57 43.62 56 48 42 4.622 5.252 7.178 22 24 36 48 40 32	PRP 54.97 50.14 44.49 38.38 56 50 46 38 4.634 4.703 5.342 6.052 22 20 22 28 46 40 30 20 68 60 52 48 Steroid 55.97 49.57 43.62 37.08 56 48 42 36 4.622 5.252 7.178 10.062 22 24 36 54 48 40 32 20	PRP 54.97 50.14 44.49 38.38 29.92 56 50 46 38 30 4.634 4.703 5.342 6.052 6.282 22 20 22 28 24 46 40 30 20 16 68 60 52 48 40 Steroid 55.97 49.57 43.62 37.08 27.51 56 48 42 36 26 4.622 5.252 7.178 10.062 11.396 22 24 36 54 62 48 40 32 20 16				

The table above displays the mean MODI score that was measured at various time intervals before and after the PRP and steroid injection in the management of DFJS patients. The disability score was 54.97 prior to the PRP injection, but

it decreased to 50.14 after 4 weeks and to 44.49 at 8 weeks. Subsequently, the disability score showed further decline at three months (38.38), and a significant decline at six months (29.92) and 1 year (21.19), all of which occurred after the PRP injection. In the treatment of DFJS patients, there is a consistent reduction in disability score after PRP injection.

The disability score was 55.97 prior to the steroid injection, but it decreased to 49.57 after 4 weeks and to 43.62 at 8 weeks. Subsequently, the disability score experienced an additional decline at three months (37.08), and a significant decline at six months (27.51) and finally disability score increased at 1 year (30.86), all of which occurred after the steroid injection. In the treatment of DFJS patients, there is a consistent reduction in disability score after steroid injection.

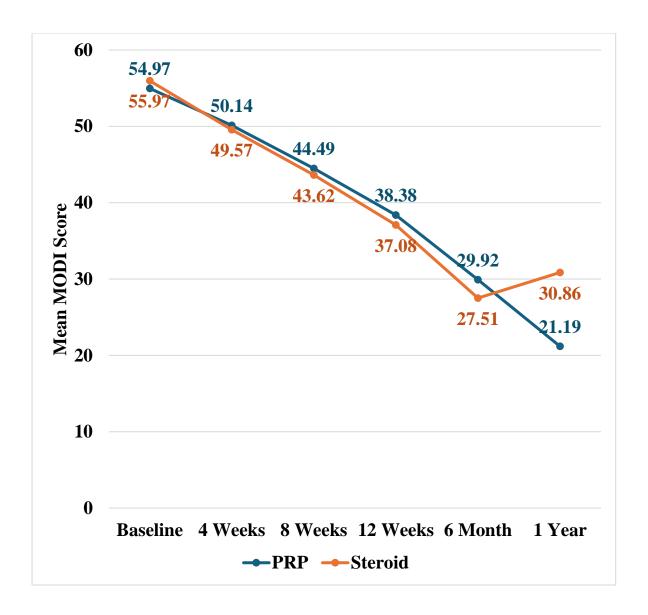


Figure 23: Line diagram showing mean MODI score at different time of assessment in both the study groups.

Table 7: Description of RMQ score at different time of assessment in both the study groups.

RMQ	Baseline	4 Weeks	8 Weeks	12 Weeks	6 Month	1 Year				
	PRP									
Mean	11.03	8.86	6.86	5.11	3.32	2.08				
Median	11	9	6	5	4	2				
S. D	1.675	1.669	1.53	1.524	1.248	0.722				
Range	8	8	7	6	4	3				
Min.	6	4	3	2	2	1				
Max.	14	12	10	8	6	4				
			Steroid							
Mean	10.97	7.92	6.27	4.51	2.54	3.97				
Median	11	8	6	4	2	4				
S. D	1.951	1.588	1.836	1.726	1.464	1.691				
Range	9	7	10	11	9	10				
Min.	7	5	4	2	1	1				
Max.	16	12	14	13	10	11				

The table above displays the mean RMQ score that was measured at various time intervals before and after the PRP and steroid injection in the management of DFJS patients. The pain related disability score (RMQ) was 11.03 prior to the

PRP injection, but it decreased to 8.86 after 4 weeks and to 6.86 at 8 weeks. The disability score declined at three months (5.11), with further significant decline at six months (3.32) and at 1 year (2.08), all of which occurred after the PRP injection. PRP injection led to consistent significant improvement in pain related disability base on RMQ score.

The pain related disability score (RMQ) was 10.97 prior to the steroid injection, but it decreased to 7.92 after 4 weeks and to 6.27 at 8 weeks. Scores reduced at three months (4.51), with further significant decline at six months (2.54) and then it increased at 1 year (3.97), all of which occurred after the steroid injection. Steroid injection led to significant improvement in pain related disability based on RMQ score.

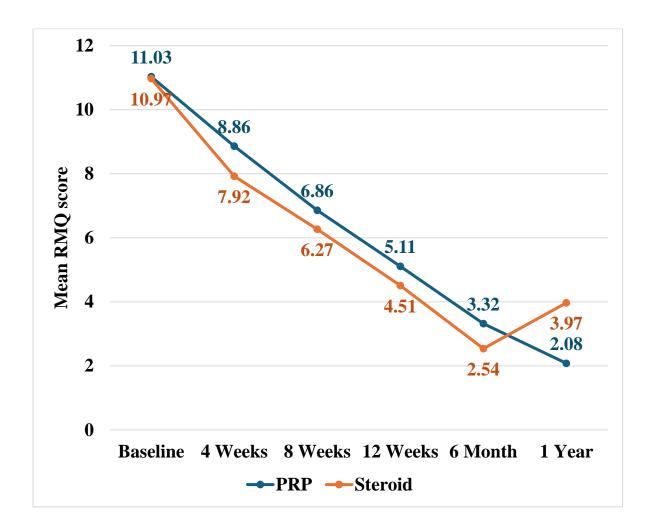


Figure 24: Line diagram showing mean RMQ score at different time of assessment in both the study groups.

Table 8: Description of PPI score at different time of assessment in both the study groups.

PPI	Baseline	4 Weeks	8 Weeks	12 Weeks	6 Month	1 Year				
	PRP									
Mean	3.89	2.92	2.11	1.73	1.03	1.03				
Median	4	3	2	2	1	1				
S. D	0.393	0.363	0.315	0.45	0.164	0.164				
Range	2	2	1	1	1	1				
Min.	3	2	2	1	1	1				
Max.	5	4	3	2	2	2				
			Steroid							
Mean	3.89	2.68	1.86	1.19	1.05	2.03				
Median	4	3	2	1	1	2				
S. D	0.516	0.58	0.419	0.397	0.229	0.44				
Range	3	3	2	1	1	2				
Min.	2	1	1	1	1	1				
Max.	5	4	3	2	2	3				

The table above displays the mean PPI score that was measured at various time intervals before and after the PRP and steroid injection in the management of DFJS patients.

The mean PPI score was 3.89 prior to the PRP injection, but it decreased to 2.92 after 4 weeks and to 2.11 at 8 weeks. At three (1.73) and six (1.03) months PPI scores significantly reduced. The PPI score remained same at 1 year (1.03). In the treatment of DFJS patients, there is a consistent reduction in PPI score after PRP injection.

The mean PPI score was 3.89 prior to the steroid injection, but it decreased to 2.68 after 4 weeks and to 1.86 at 8 weeks. Subsequently, the pain score showed an additional decline at three months (1.19), a significant decline at six months (1.05) and finally pain score increased at 1 year (2.03), all of which occurred after the steroid injection. In the treatment of DFJS patients, there is a consistent reduction in pain score after steroid injection.

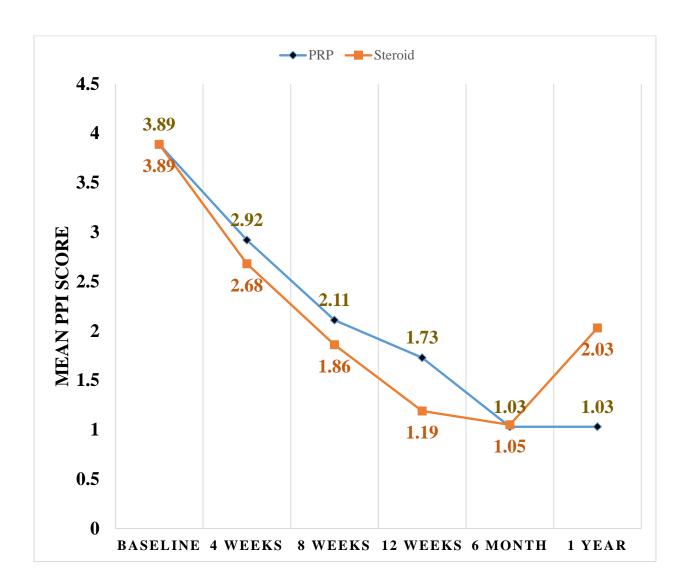


Figure 25: Line diagram showing mean PPI score at different time of assessment in both the study groups.

Table 9: Description of SF-12 score at different time of assessment in both the study groups

SF-12	Baseline	4 Weeks	8 Weeks	12 Weeks	6 Month	1 Year				
	PRP									
Mean	50.76	55.35	60.11	64.97	70.54	75.35				
Median	50	56	60	64	70	74				
S. D	5.193	5.165	5.076	4.387	3.877	4.191				
Range	20	20	20	18	16	18				
Min.	40	44	50	56	64	70				
Max.	60	64	70	74	80	88				
			Steroid							
Mean	49.08	55.3	60.19	65.05	71.03	66.65				
Median	50	56	60	66	72	68				
S. D	7.143	6.737	6.732	6.888	5.747	5.926				
Range	26	30	30	32	32	36				
Min.	34	38	40	42	48	48				
Max.	60	68	70	74	80	84				

The table above displays the mean SF-12 score that was measured at various time intervals before and after the PRP and steroid injection in the management of DFJS patients.

The mean SF-12 score was 50.76 prior to the PRP injection, but it increased to 55.35 after 4 weeks and to 60.11 at 8 weeks. The QOL showed improvement at three months (64.97), and a significant increase in score at six months (70.54) with consistent improvement up to 1 year follow-up (75.35), all of which occurred after the PRP injection. In the treatment of DFJS patients, there is a consistent increase in SF-12 score after PRP injection.

The mean SF-12 score was 49.08 prior to the steroid injection, but it increased to 55.3 after 4 weeks and to 60.19 at 8 weeks. Subsequently, the QOL improved at three months (65.05) with significant incline at six months (71.03) and finally SF-12 score decreased at 1 year (66.65), all of which occurred after the steroid injection. Following steroid injection there is consistent improvement in QOL based on SF-12 score.

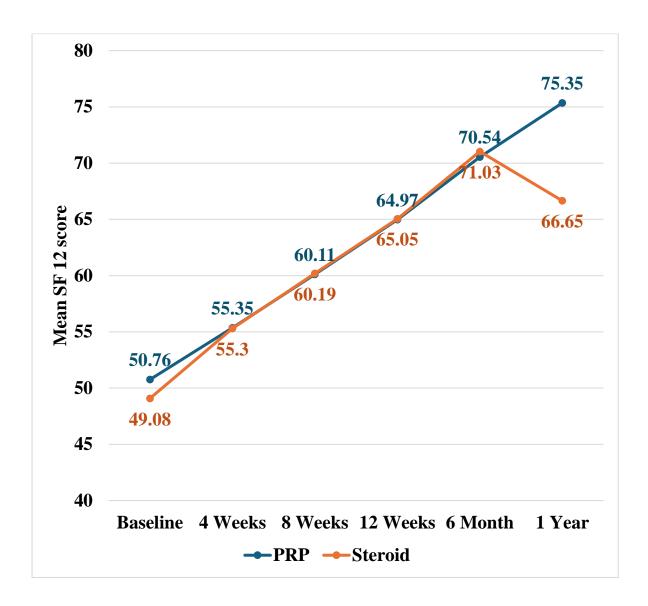


Figure 26: Line diagram showing mean SF-12 score at different time of assessment in both the study groups.

Table 10: Comparison of differences in VAS score before and after the procedure in both the study groups at each of the subsequent follow up period.

Group	VAS	S Score	Mean	S. D	Mean diff.	P value
	Pair 1	Baseline	6.65	0.676	1.595	0.0001
		4 Weeks	5.05	0.575	1.575	0.0001
	Pair 2	Baseline	6.65	0.676	2.730	0.0001
		8 Weeks	3.92	0.493	2.730	0.0001
PRP	Pair 3	Baseline	6.65	0.676	3.757	0.0001
TKI		12 Weeks	2.89	0.516	3.737	0.0001
	Pair 4	Baseline	6.65	0.676	4.811	0.0001
	I all +	6 Month	1.84	0.501	7.011	0.0001
	Pair 5	Baseline	6.65	0.676	5.595	0.0001
		1 Year	1.05	0.229		0.0001
	Pair 1	Baseline	6.76	0.76	2.405	0.0001
		4 Weeks	4.35	0.676	2.403	0.0001
	Pair 2	Baseline	6.76	0.76	3.486	0.0001
		8 Weeks	3.27	0.56	3.400	0.0001
Steroid	Pair 3	Baseline	6.76	0.76	4.432	0.0001
Steroid		12 Weeks	2.32	0.58	7.732	0.0001
	Pair 4	Baseline	6.76	0.76	5.459	0.0001
	1 411 7	6 Month	1.3	0.52	3.737	0.0001
	Pair 5	Baseline	6.76	0.76	4.108	0.0001
		1 Year	2.65	0.676		0.0001

The Paired T test comparison of pain score changes before and after the procedure at one, two, three and six months & at one year for both research groups is displayed in the above table.

Prior to PRP injection, the mean pain score was 6.65; after 4 weeks, it dropped to 5.05, and the Paired T test indicated that this change in mean pain score as determined by the VAS was statistically relevant (P value 0.0001). The mean pain score prior to PRP injection was 6.65, and it dropped to 3.92 after eight weeks. The Paired T test indicated that this difference in mean pain score as determined by the VAS was statistically relevant (P value 0.0001). The average pain score prior to PRP injection was 6.65, and it fell to 2.89 at 12 weeks. This difference in mean pain score as determined by VAS was statistically significant by Paired T test (P value 0.0001).

The mean pain score before PRP injection was 6.65 and it decreased to 1.84 at 6 months and this difference in mean pain score as measured by VAS was statistically significant by Paired T test (P value 0.0001). The mean pain score before PRP injection was 6.65 and it decreased to 1.05 at 1 year and this difference in mean pain score as measured by VAS was statistically significant by Paired T test (P value 0.0001).

The mean pain score before steroid injection was 6.76 and it decreased to 4.35 at 4 weeks and this difference in mean pain score as measured by VAS was statistically relevant by Paired T test (P value 0.0001). Average pain score

before steroid injection was 6.76 and it decreased to 3.27 at 8 weeks and this difference in mean pain score as measured by VAS was statistically relevant by Paired T test (P value 0.0001). The mean pain score before steroid injection was 6.76 and it decreased to 2.32 at 12 weeks and this difference in mean pain score as measured by VAS was statistically significant by Paired T test (P value 0.0001). The mean pain score before steroid injection was 6.76 and it decreased to 1.3 at 6 months and this difference in mean pain score as measured by VAS was statistically significant by Paired T test (P value 0.0001). The mean pain score before steroid injection was 6.76 and it decreased to 2.65 at 1 year and this difference in mean pain score as measured by VAS was statistically significant by Paired T test (P value 0.0001).

There is a significant decrease in pain in both the groups. PRP is better than steroid in reducing perceived pain (VAS) at long term (1 year), whereas steroid is better than PRP in reducing perceived pain at short term.

Table 11: Comparison of differences in MODI score before and after the procedure in both the study groups during the follow up period by Paired T test.

GROUP	MOI	OI score	Mean	S. D	Mean diff.	P value
	Pair 1	Baseline	54.97	4.634	4.838	0.0001
	T all 1	4 Weeks	50.14	4.703		
	Pair 2	Baseline	54.97	4.634	10.486	0.0001
		8 Weeks	44.49	5.342		
PRP	Pair 3	Baseline	54.97	4.634	16.595	0.0001
T KI	1 an 3	12 Weeks	38.38	6.052		
	Pair 4	Baseline	54.97	4.634	25.054	0.0001
	1 411 +	6 Month	29.92	6.282		
	Pair 5	Baseline	54.97	4.634	33.784	0.0001
		1 Year	21.19	5.915		
	Pair 1	Baseline	55.97	4.622	6.405	0.0001
	1 an 1	4 Weeks	49.57	5.252		
	Pair 2	Baseline	55.97	4.622	12.351	0.0001
		8 Weeks	43.62	7.178		
Steroid	Pair 3	Baseline	55.97	4.622	18.892	0.0001
Steroid	1 an 3	12 Weeks	37.08	10.062		
	Pair 4	Baseline	55.97	4.622	28.459	0.0001
	1 411 4	6 Month	27.51	11.396		
	Pair 5	Baseline	55.97	4.622	25.108	0.0001
		1 Year	30.86	8.826		

The above table shows the comparison of differences in disability score before and after the procedure in both the study groups at one to three months, 6 months & at 1 year by Paired T test.

The mean disability score before PRP injection was 54.97 and it decreased to 50.14 at 4 weeks and this difference in mean disability score as measured by MODI was statistically relevant by Paired T test (P value 0.0001). The mean disability score before PRP injection was 54.97 and it decreased to 44.49 at 8 weeks and this difference in mean disability score as measured by MODI was statistically significant by Paired T test (P value 0.0001). The mean disability score before PRP injection was 54.97 and it decreased to 38.38 at 12 weeks and this difference in mean disability score as measured by MODI was statistically relevant by Paired T test (P value 0.0001). The mean disability score before PRP injection was 54.97 and it decreased to 29.92 at 6 months and this difference in mean disability score as measured by MODI was statistically significant by Paired T test (P value 0.0001). The mean disability score before PRP injection was 54.97 and it decreased to 21.19 at 1 year and this difference in mean disability score as measured by MODI was statistically relevant by Paired T test (P value 0.0001).

The mean disability score before steroid injection was 55.97 and it decreased to 49.57 at 4 weeks and this difference in mean disability score as measured by MODI was statistically significant by Paired T test (P value 0.0001). The mean

disability score before steroid injection was 55.97 and it decreased to 43.62 at 8 weeks and this difference in mean disability score as measured by MODI was statistically significant by Paired T test (P value 0.0001). The mean disability score before steroid injection was 55.97 and it decreased to 37.08 at 12 weeks and this difference in mean disability score as measured by MODI was statistically significant by Paired T test (P value 0.0001). The mean disability score before steroid injection was 55.97 and it decreased to 27.51 at 6 months and this difference in mean disability score as measured by MODI was statistically significant by Paired T test (P value 0.0001). The mean disability score before steroid injection was 55.97 and it decreased to 30.86 at 1 year and this difference in mean disability score as measured by MODI was statistically significant by Paired T test (P value 0.0001).

There is significant decrease in disability in both the groups. PRP is better than steroid in reducing perceived disability (MODI) at long term (1 year), whereas steroid is better than PRP in reducing perceived disability at short term.

Table 12: Comparison of differences in RMQ score before and after the procedure at each follow-up in both the study groups by Paired T test.

GROUP	RM	Q Score	Mean	S. D	Mean diff.	P value
	Pair 1	Baseline	11.03	1.675	2.162	0.0001
		4 Weeks	8.86	1.669	2.102	0.0001
	Pair 2	Baseline	11.03	1.675	4.162	0.0001
		8 Weeks	6.86	1.53	7.102	0.0001
PRP	Pair 3	Baseline	11.03	1.675	5.919	0.0001
T KI		12 Weeks	5.11	1.524		0.0001
	Pair 4	Baseline	11.03	1.675	7.703	0.0001
	I all 4	6 Month	3.32	1.248	7.703	0.0001
	Pair 5	Baseline	11.03	1.675	8.946	0.0001
		1 Year	2.08	0.722		0.0001
	Pair 1	Baseline	10.97	1.951	3.054	0.0001
		4 Weeks	7.92	1.588	3.034	0.0001
	Pair 2	Baseline	10.97	1.951	4.703	0.0001
		8 Weeks	6.27	1.836	4.703	0.0001
Steroid	Pair 3	Baseline	10.97	1.951	6.459	0.0001
Steroid	T un 3	12 Weeks	4.51	1.726	0.137	0.0001
	Pair 4	Baseline	10.97	1.951	8.432	0.0001
	I ull T	6 Month	2.54	1.464	0.732	0.0001
	Pair 5	Baseline	10.97	1.951	7.000	0.0001
		1 Year	3.97	1.691	.000	0.0001

The mean pain related disability score prior to PRP injection was 11.03 and it decreased to 8.86 at 4 weeks and this difference as measured by RMQ was statistically relevant by Paired T test (P value 0.0001). The mean pain related disability score before PRP injection was 11.03 and it decreased to 6.86 at 8 weeks and this difference in average pain related disability score as measured by RMQ was statistically relevant by Paired T test (P value 0.0001). The mean pain related disability score before PRP injection was 11.03 and it decreased to 5.11 at 12 weeks and the difference as measured by RMQ was statistically relevant by Paired T test (P value 0.0001). The mean pain related disability score before PRP injection was 11.03 and it decreased to 3.32 at 6 months and this difference in average related disability score as measured by RMQ was statistically relevant by Paired T test (P value 0.0001). The mean pain related disability score before PRP injection was 11.03 and it decreased to 2.08 at 1 year and this difference in mean pain related disability score as measured by RMQ was statistically relevant by Paired T test (P value 0.0001).

The mean pain related disability score before steroid injection was 10.97 and it decreased to 7.92 at 4 weeks and this difference in average related disability score as measured by RMQ was statistically relevant by Paired T test (P value 0.0001). The average pain related disability score before steroid injection was 10.97 and it decreased to 6.27 at 8 weeks and this difference in average pain related disability score as measured by RMQ was statistically relevant by Paired

T test (P value 0.0001). The average pain related disability score before steroid injection was 10.97 and it decreased to 4.51 at 12 weeks and this difference in mean pain related disability score as measured by RMQ was statistically relevant by Paired T test (P value 0.0001). The average pain related disability score before steroid injection was 10.97 and it decreased to 2.54 at 6 months and this difference in mean pain related disability score as measured by RMQ was statistically relevant by Paired T test (P value 0.0001). Average pain related disability score before steroid injection was 10.97 and it decreased to 3.97 at 1 year and this difference in average pain related disability score as measured by RMQ was statistically significant by Paired T test (P value 0.0001).

There is marked decrease in self-rated physical disability in both the groups. PRP is better than Steroid in reducing self-rated physical disability (RMQ) at long term (1 year), whereas steroid is better than PRP in reducing self-rated physical disability at short term.

Table 13: Comparison of differences in PPI score pre- and post-procedure during follow-up in both groups by Paired T test.

GROUP	PP	I Score	Mean	S. D	Mean diff.	P value
	Pair 1	Baseline	3.89	0.393	0.973	0.0001
	T un 1	4 Weeks	2.92	0.363	0.573	0.0001
	Pair 2	Baseline	3.89	0.393	1.784	0.0001
		8 Weeks	2.11	0.315	1.704	.,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,
PRP	Pair 3	Baseline	3.89	0.393	2.162	0.0001
	T un 3	12 Weeks	1.73	0.45	2.102	0.0001
	Pair 4	Baseline	3.89	0.393	2.865	0.0001
	ran 4	6 Month	1.03	0.164	2.003	0.0001
	Pair 5	Baseline	3.89	0.393	2.865	0.0001
		1 Year	1.03	0.164		0.0001
	Pair 1	Baseline	3.89	0.516	1.216	0.0001
	T uii 1	4 Weeks	2.68	0.58	1.210	0.0001
	Pair 2	Baseline	3.89	0.516	2.027	0.0001
		8 Weeks	1.86	0.419	2.027	0.0001
Steroid	Pair 3	Baseline	3.89	0.516	2.703	0.0001
2001010		12 Weeks	1.19	0.397	2.708	0.0001
	Pair 4	Baseline	3.89	0.516	2.838	0.0001
	1 1111	6 Month	1.05	0.229	2.330	0.0001
	Pair 5	Baseline	3.89	0.516	1.865	0.0001
		1 Year	2.03	0.44	1.000	3.0001

The above table shows the comparison of differences in pain score before and after the procedure in both the study groups during the follow-up period by Paired T test.

The mean pain score before PRP injection was 3.89 and it decreased to 2.92 at 4 weeks and this difference in mean pain score as measured by PPI was statistically significant by dependent samples T test (P value 0.0001). The mean pain score before PRP injection was 3.89 and it decreased to 2.11 at 8 weeks and this difference in mean pain score as measured by PPI was statistically relevant by Paired T test (P value 0.0001). The mean pain score before PRP injection was 3.89 and it decreased to 1.73 at 12 weeks and this difference in mean pain score as measured by PPI was statistically relevant by dependent sample T test (P value 0.0001). The mean pain score before PRP injection was 3.89 and it decreased to 1.03 at 6 months and this difference in mean pain score as measured by PPI was statistically relevant by dependent sample T test (P value 0.0001). The mean pain score before PRP injection was 3.89 and it decreased to 1.03 at 1 year and this difference in mean pain score as measured by PPI was statistically relevant by dependent sample T test (P value 0.0001).

The mean pain score before steroid injection was 3.89 and it decreased to 2.68 at 4 weeks and this difference in mean pain score as measured by PPI was statistically significant by Paired T test (P value 0.0001).

The mean pain score before steroid injection was 3.89 and it decreased to 1.86 at 8 weeks and this difference in mean pain score as measured by PPI was statistically relevant by Paired T test (P value 0.0001).

The mean pain score before steroid injection was 3.89 and it decreased to 1.19 at 12 weeks and this difference in mean pain score as measured by PPI was statistically relevant by Paired T test (P value 0.0001).

The mean pain score before steroid injection was 3.89 and it decreased to 1.05 at 6 months and this difference in mean pain score as measured by PPI was statistically relevant by Paired T test (P value 0.0001).

The mean pain score before steroid injection was 3.89 and it decreased to 2.03 at 1 year and this difference in mean pain score as measured by PPI was statistically significant by Paired T test (P value 0.0001).

There is significant decrease in pain in both the groups. PRP is better than steroid in reducing perceived pain (PPI) at long term (1 year), whereas steroid is better than PRP in reducing perceived pain at short term.

Table 14: Comparison of differences in SF-12 score before and after the procedure in both the study groups during the follow-up period by Paired T test.

GROUP	S	SF 12	Mean	S. D	Mean diff.	P value
	Pair 1	Baseline	50.76	5.193	-4.595	0.0001
	T un 1	4 Weeks	55.35	5.165	1.575	0.0001
	Pair 2	Baseline	50.76	5.193	-9.351	0.0001
		8 Weeks	60.11	5.076	7.551	0.0001
PRP	Pair 3	Baseline	50.76	5.193	-14.216	0.0001
	T un 3	12 Weeks	64.97	4.387		0.0001
	Pair 4	Baseline	50.76	5.193	-19.784	0.0001
	ran 4	6 Month	70.54	3.877	17.704	0.0001
	Pair 5	Baseline	50.76	5.193	-24.595	0.0001
		1 Year	75.35	4.191		0.0001
	Pair 1	Baseline	49.08	7.143	-6.216	0.0001
	T un 1	4 Weeks	55.3	6.737	0.210	0.0001
	Pair 2	Baseline	49.08	7.143	-11.108	0.0001
	Tun 2	8 Weeks	60.19	6.732	11.100	0.0001
Steroid	Pair 3	Baseline	49.08	7.143	-15.973	0.0001
Steroid		12 Weeks	65.05	6.888	13.773	0.0001
	Pair 4	Baseline	49.08	7.143	-21.946	0.0001
		6 Month	71.03	5.747	21.710	0.0001
	Pair 5	Baseline	49.08	7.143	-17.568	0.0001
		1 Year	66.65	5.926		3.5501

The above table shows the comparison of differences in QOL score before and after the procedure in both the study groups during the follow-up period by Paired T test. The mean QOL score before PRP injection was 50.76 and it increased to 55.35 at 4 weeks and this difference in mean QOL score as measured by SF-12 was statistically significant by Paired T test (P value 0.0001).

The mean QOL score before PRP injection was 50.76 and it increased to 60.11 at 8 weeks and this difference in mean QOL score as measured by SF-12 was statistically significant by Paired T test (P value 0.0001). The mean QOL score before PRP injection was 50.76 and it improved to 64.97 at 12 weeks and this difference in mean QOL score as measured by SF-12 was statistically relevant by Paired T test (P value 0.0001). The mean QOL score before PRP injection was 50.76 and it increased to 70.54 at 6 months and this difference in mean QOL score as measured by SF-12 was statistically relevant by Paired T test (P value 0.0001). The mean QOL score before PRP injection was 50.76 and it improved to 75.35 at 1 year and this difference in mean QOL score as measured by SF-12 was statistically relevant by Paired T test (P value 0.0001).

The mean QOL score before steroid injection was 49.08 and it increased to 55.3 at 4 weeks and this difference in mean QOL score as measured by SF-12 was statistically significant by Paired T test (P value 0.0001). The mean QOL score before steroid injection was 49.08 and it increased to 60.19 at 8 weeks and

this difference in mean QOL score as measured by SF-12 was statistically significant by Paired T test (P value 0.0001). The mean QOL score before steroid injection was 49.08 and it increased to 65.05 at 12 weeks and this difference in mean QOL score as measured by SF-12 was statistically significant by Paired T test (P value 0.0001). The mean QOL score before steroid injection was 49.08 and it increased to 71.03 at 6 months and this difference in mean QOL score as measured by SF-12 was statistically significant by Paired T test (P value 0.0001). The mean QOL score before steroid injection was 49.08 and it increased to 66.65 at 1 year and this difference in mean QOL score as measured by SF-12 was statistically significant by Paired T test (P value 0.0001).

There is significant improvement in health-related QOL both the groups. PRP is better than steroid in improving health-related QOL (SF-12) at long term (1 year), whereas steroid is better than PRP in improving health-related QOL at short term.

Table 15: Comparison of differences in VAS score between the study groups before and after the procedure during the follow-up period by Independent T test.

Category	Mean			
	Mean	n Deviation	Difference	P value
PRP	6.65	0.676	-0.108	0.52
Steroid	6.76	0.76		
PRP	5.05	0.575	0.703	0.0001
Steroid	4.35	0.676	0.703	
PRP	3.92	0.493	0.649	0.0001
Steroid	3.27	0.56	0.049	
PRP	2.89	0.516	0.568	0.0001
Steroid	2.32	0.58		
PRP	1.84	0.501	0.541	0.0001
Steroid	1.3	0.52	0.541	
PRP	1.05	0.229	-1.595	0.0001
Steroid	2.65	0.676	1.070	0.0001
	Steroid PRP Steroid PRP Steroid PRP Steroid PRP Steroid PRP	Steroid 6.76 PRP 5.05 Steroid 4.35 PRP 3.92 Steroid 3.27 PRP 2.89 Steroid 2.32 PRP 1.84 Steroid 1.3 PRP 1.05	Steroid 6.76 0.76 PRP 5.05 0.575 Steroid 4.35 0.676 PRP 3.92 0.493 Steroid 3.27 0.56 PRP 2.89 0.516 Steroid 2.32 0.58 PRP 1.84 0.501 Steroid 1.3 0.52 PRP 1.05 0.229	Steroid 6.76 0.76 PRP 5.05 0.575 Steroid 4.35 0.676 PRP 3.92 0.493 Steroid 3.27 0.56 PRP 2.89 0.516 Steroid 2.32 0.58 PRP 1.84 0.501 Steroid 1.3 0.52 PRP 1.05 0.229 -1.595

The above table shows the comparison of differences in pain score between the study groups before and after the procedure during follow-up period by Independent T test.

The average pain score pre-injection in PRP group was 6.65 while the average pain score pre-injection in steroid group was 6.76. This variance in pain score before the injection between both study groups was not statistically relevant by Independent T test (p value 0.52).

The mean pain score 4 weeks after the injection in PRP group was 5.05 while the mean pain score 4 weeks after the injection in steroid group was 4.35. This difference in pain score at 4 weeks after the injection between the two study groups was statistically relevant by Independent T test (p value 0.0001).

The mean pain score 8 weeks after the injection in PRP group was 3.92 while the mean pain score 8 weeks after the injection in steroid group was 3.27. This difference in pain score at 8 weeks after the injection between the two study groups was statistically relevant by Independent T test (p value 0.0001).

The mean pain score 12 weeks after the injection in PRP group was 2.89 while in steroid group it was 2.32. This variation in pain score at 12 weeks after the injection between the two study groups was statistically relevant by Independent T test (p value 0.0001).

The mean pain score 6 months post injection in PRP group was 1.84 while in steroid group it was 1.3. This difference in pain score at 6 months after the injection between the two study groups was statistically relevant by Independent T test (p value 0.0001).

The mean pain score 1 year after the injection in PRP group was 1.05 while the mean pain score 1 year after the injection in steroid group was 2.65. This difference in pain score at 1 year post injection between the two study groups was statistically relevant by Independent T test (p value 0.0001).

Based on the above findings it was inferred that PRP is better than Steroid in reducing perceived pain (VAS) at long term (1 year), whereas steroid is better than PRP in reducing perceived pain at short term (1 month to 6 months).

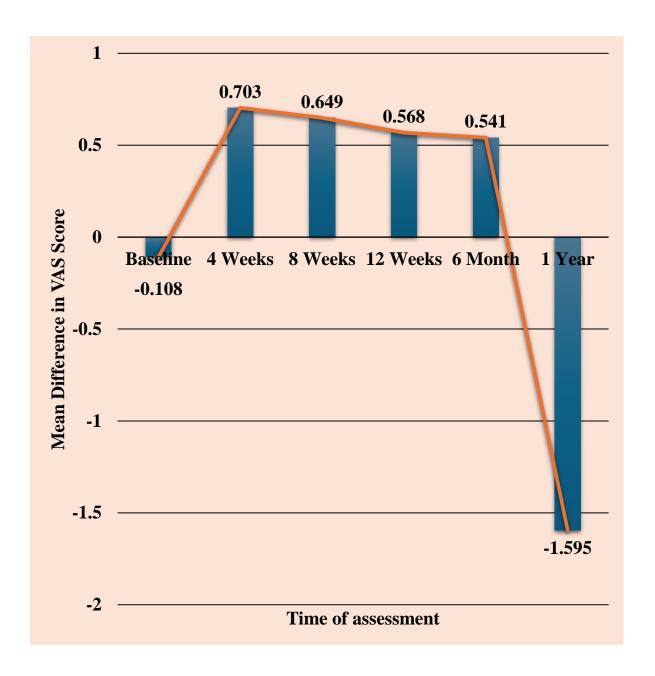


Figure 27: Combo diagram showing differences in VAS score between the study groups before and after the procedure during follow-up period by Independent T test.

Table 16: Comparison of differences in MODI score between the study groups before and after the procedure at 1 month, 2 month, 3 months, 6 months & 1 year by Independent T test.

MODI	Category	Mean	Std.	Mean	P value
WODI	Category	Wican	Deviation	Difference	1 value
Baseline	PRP	54.97	4.634	-1.000	0.356
	Steroid	55.97	4.622		
4 Weeks	PRP	50.14	4.703	0.568	0.626
	Steroid	49.57	5.252		
8 Weeks	PRP	44.49	5.342	0.865	0.558
	Steroid	43.62	7.178		
12 Weeks	PRP	38.38	6.052	1.297	0.504
	Steroid	37.08	10.062		
6 Month	PRP	29.92	6.282	2.405	0.265
0 1/1011411	Steroid	27.51	11.396	20.00	3.235
1 Year	PRP	21.19	5.915	-9.676	0.0001
1 1001	Steroid	30.86	8.826	7.070	0.0001

The above table shows the comparison of differences in disability score between the study groups before and after the procedure at 1 month, 2 months, 3 months, 6 months & at 1 year by Independent T test.

The PRP group had a mean disability score of 54.97 prior to injection, whereas the steroid group had an average disability score of 55.97 prior to injection. According to the Independent T test, there was no statistically relevant difference in the impairment scores of the two research groups prior to the injection (p value 0.356).

Four weeks following the injection, mean disability score in the steroid group was 49.57, but mean score in the PRP group was 50.14. According to the Independent T test, the difference in the two study groups' impairment scores four weeks after the injection was not statistically significant (p value 0.626).

Four weeks following the injection, the mean disability score for the PRP group was 50.14, whereas the mean score for the steroid group was 49.57. According to the Independent T test, there was no statistically relevant change in the impairment scores between the two study groups four weeks after the injection (p value 0.626).

The mean disability scores 12 weeks after the injection in PRP group was 38.38 while the mean disability score 12 weeks after the injection in steroid group was 37.08. This difference in disability score at 12 weeks after the injection between the study groups was not statistically relevant by Independent T test (p value 0.504).

The mean disability scores 6 months post injection in PRP group was 29.92 while the mean disability score 6 months after the injection in steroid group was

27.51. This difference in disability score at 6 months after the injection between both study groups was not statistically relevant by Independent T test (p value 0.265).

The mean disability scores 1 year after the injection in PRP group was 21.19 while the mean disability score 1 year after the injection in steroid group was 30.86. This difference in disability score at 1 year after the injection between the two study groups was statistically relevant by Independent T test (p value 0.0001).

Based on the above findings it was inferred that PRP was better than Steroid in reducing perceived disability (MODI) at long term (1 year), and it was statistically significant. Steroid is better than PRP in reducing perceived disability at short term (1 month to 6 months), but it was not statistically significant. Hence there is no difference in improvement of disability between the PRP and steroid groups from 1 month to 6 months.

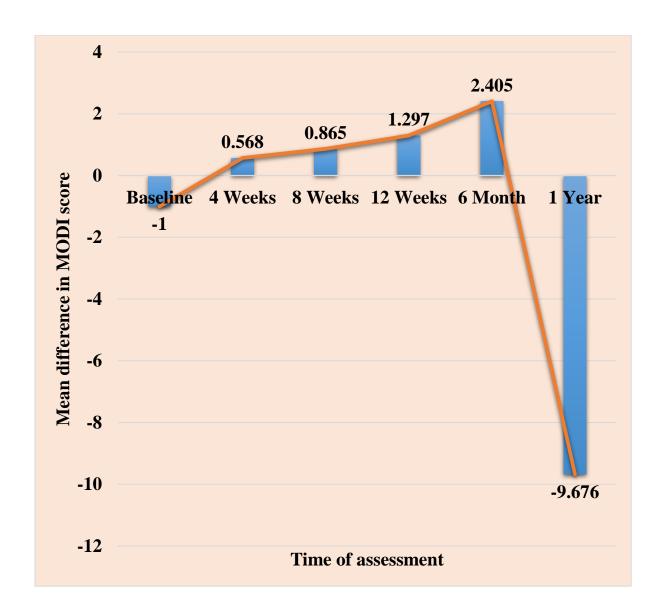


Figure 28: Combo diagram showing differences in MODI score between the study groups before and after the procedure during follow-up by Independent T test.

Table 17: Comparison of differences in RMQ score between the study groups before and after the procedure during follow-up by Independent T test.

RMQ	Category	Mean	Std. Deviation	Mean Difference	P value
	PRP	11.03	1.675		
Baseline	Steroid	10.97	1.951	0.054	0.899
4 Weeks	PRP	8.86	1.669	0.946	0.015
+ Weeks	Steroid	7.92	1.588	0.946	0.013
8 Weeks	PRP	6.86	1.53	0.595	0.135
	Steroid	6.27	1.836		
12 Weeks	PRP	5.11	1.524	0.595	0.121
	Steroid	4.51	1.726		
6 Month	PRP	3.32	1.248	0.784	0.016
	Steroid	2.54	1.464		
1 Year	PRP	2.08	0.722	-1.892	0.0001
	Steroid	3.97	1.691		

Mean pain related disability score before the injection in PRP group was 11.03 while the mean pain related disability score prior injection in steroid group was 10.97. This difference in pain related disability score before the

injection between the two study groups was not statistically significant by Independent T test (p value 0.899).

Four weeks following the injection, the mean pain-related disability score for the PRP group was 8.86, whereas in the steroid group it was 7.92. Based on the Independent T test, there was a statistically relevant difference (p value of 0.015) in the pain-related disability score between the two study groups four weeks post-injection.

The mean pain related disability score 8 weeks after the injection in PRP group was 6.86 while the mean pain related disability score 8 weeks after the injection in steroid group was 6.27. This difference in pain related disability score at 8 weeks after the injection between the two study groups was not statistically significant by Independent T test (p value 0.135).

The mean pain related disability score 12 weeks after the injection in PRP group was 5.11 while the mean pain related disability score 12 weeks after the injection in steroid group was 4.51. This difference in pain related disability score at 12 weeks after the injection between the two study groups was not statistically significant by Independent T test (p value 0.121).

Six months following injection, the mean pain-related disability score in the PRP group was 3.32, whereas the mean pain-related disability score in the steroid group was 2.54. By using the Independent T test, the two study groups'

pain-related impairment scores at six months following the injection differed, and this difference was statistically relevant (p value 0.016).

The mean pain related disability score 1 year after the injection in PRP group was 2.08 while the mean pain related disability score 1 year after the injection in steroid group was 3.97. This difference in pain related disability score at 1 year after the injection between the two study groups was statistically relevant by Independent T test (p value 0.0001).

Based on the above findings it was inferred that PRP is better than Steroid in reducing self-rated physical disability (RMQ) at long term (6 months and 1 year), whereas steroid is better than PRP in reducing self-rated physical disability at 4 weeks. Steroid is better than PRP in reducing self-rated physical disability at 8 and 12 weeks but it was not statistically relevant and there was no difference between the two groups.

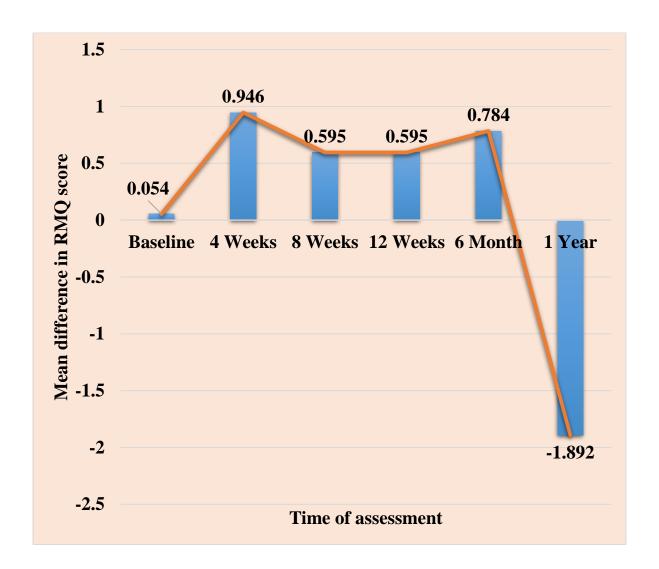


Figure 29: Combo diagram showing differences in RMQ score between the study groups before and after the procedure at 1 month, 2 month, 3 months, 6 months & at 1 year by Independent T test.

Table 18: Comparison of differences in PPI score between the study groups before and after the procedure at each follow-up by Independent T test.

PPI	Category	Mean	Std. Deviation	Mean Difference	P value
Baseline	PRP	3.89	0.393	0.000	1.000
Buschine	Steroid	3.89	0.516	0.000	1.000
4 Weeks	PRP	2.92	0.363	0.243	0.034
,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	Steroid	2.68	0.58		0.031
8 Weeks	PRP	2.11	0.315	0.243	0.006
	Steroid	1.86	0.419		
12 Weeks	PRP	1.73	0.45	0.541	0.0001
	Steroid	1.19	0.397		
6 Month	PRP	1.03	0.164	-0.027	0.562
	Steroid	1.05	0.229	0.027	
1 Year	PRP	1.03	0.164	1.000	0.0001
	Steroid	2.03	0.44		

The above table shows the comparison of differences in pain score (measure by PPI score) between the study groups before and after the procedure by Independent T test.

Mean pain score prior to injection in PRP and steroid groups was 3.89. Both groups had a similar pain score (measure by PPI score) before the injection and was not statistically relevant by Independent T test (p value 1.000).

The mean pain score 4 weeks after the injection in PRP group was 2.92 while the mean pain score 4 weeks after the injection in steroid group was 2.68. This difference in pain score (measure by PPI score) at 4 weeks post-injection between the groups was statistically relevant by Independent T test (p value 0.034).

Mean pain score 8 weeks after the injection in PRP group was 2.11 while the mean pain score 8 weeks after the injection in steroid group was 1.86. This difference in pain score (measure by PPI score) at 8 weeks after the injection between the two study groups was statistically relevant by Independent T test (p value 0.006).

The average pain score 12 weeks after the injection in PRP group was 1.73 while the mean pain score 12 weeks after the injection in steroid group was 1.19. This difference in pain score (measure by PPI score) at 12 weeks after the injection between the two study groups was statistically relevant by Independent T test (p value 0.0001).

The average pain score 6 months after the injection in PRP group was 1.03 while in steroid group it was 1.05. This difference in pain score (measure by PPI

score) at 6 months after the injection between the two study groups was not statistically relevant by Independent T test (p value 0.0562).

The average pain score 1 year after the injection in PRP group was 1.03 while the mean pain score 1 year after the injection in steroid group was 2.03. This difference in pain score (measure by PPI score) at 1 year after the injection between the two study groups was statistically relevant by Independent T test (p value 0.0001).

Based on the above findings it was inferred that PRP is better than steroid in reducing perceived pain (PPI) at long term (1 year), whereas steroid is better than PRP in reducing perceived pain at short term (4, 8 and 12 weeks). Steroid was better than PRP in reducing self-rated physical disability at 6 months, though not statistically significant.

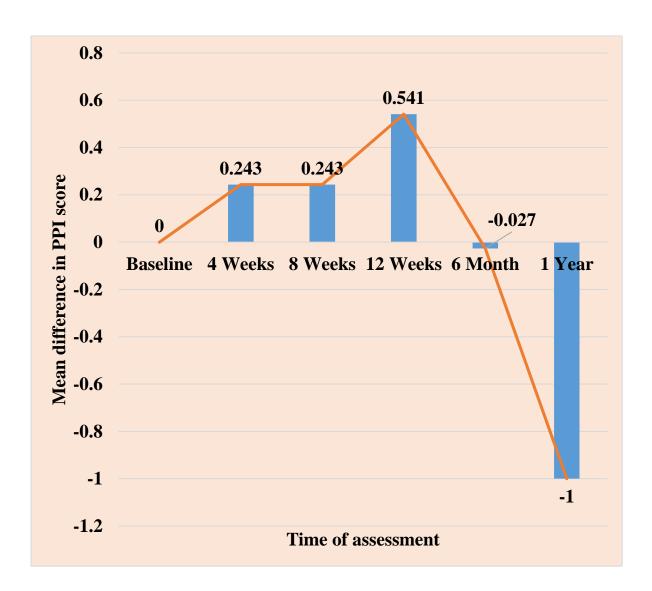


Figure 30: Combo diagram showing differences in PPI score between the study groups before and after the procedure during follow-up period Independent T test.

Table 19: Comparison of differences in SF-12 score between the study groups before and after the procedure during the follow-up period by Independent T test.

SF 12	Category	Mean	Std.	Mean	P value
			Deviation	Difference	
Baseline	PRP	50.76	5.193	1.676	0.252
	Steroid	49.08	7.143		
4 Weeks	PRP	55.35	5.165	0.054	0.969
	Steroid	55.3	6.737	0.054	
8 Weeks	PRP	60.11	5.076	-0.081	0.954
	Steroid	60.19	6.732		
12 Weeks	PRP	64.97	4.387	-0.081	0.952
	Steroid	65.05	6.888	, 0,001	3,702
6 Month	PRP	70.54	3.877	-0.486	0.671
0 1/1011	Steroid	71.03	5.747	0.400	31371
1 Year	PRP	75.35	4.191	8.703	0.0001
1 1001	Steroid	66.65	5.926	0.705	3.0001

The mean health related QOL score before the injection in PRP group was 50.76 while the mean health related QOL score before the injection in steroid group was 49.08. This difference in pain related disability score before the

injection between both study groups was not statistically significant by Independent T test (p value 0.252).

The mean health related QOL score 4 weeks after the injection in PRP group was 55.35 while the mean health related QOL score 4 weeks after the injection in steroid group was 55.3. This difference in pain related disability score at 4 weeks after the injection between both study groups was not statistically relevant by Independent T test (p value 0.969).

The mean health related QOL score 8 weeks after the injection in PRP group was 60.11 while the mean health related QOL score 8 weeks after the injection in steroid group was 60.19. This difference in pain related disability score at 8 weeks after the injection both study groups was not statistically relevant by Independent T test (p value 0.954).

The mean health related QOL score 12 weeks after the injection in PRP group was 64.97 while the mean health related QOL score 12 weeks after the injection in steroid group was 65.05. This difference in pain related disability score at 12 weeks after the injection between both study groups was not statistically relevant by Independent T test (p value 0.952).

The mean health related QOL score 6 months following injection in PRP group was 70.54 while the mean health related QOL score 6 months post injection in steroid group was 71.03. This difference in pain related disability

score at 6 months after the injection between both study groups was statistically relevant by Independent T test (p value 0.0671).

The mean health related QOL score 1 year after the injection in PRP group was 75.35 while the mean health related QOL score 1 year after the injection in steroid group was 66.65. This difference in pain related disability score at 1 year after the injection between the two study groups was statistically significant by Independent T test (p value 0.0001).

Based on the above findings it was inferred that PRP was better than Steroid in improving health-related QOL (SF-12) at long term (1 year), and it was statistically significant. Steroid was better than PRP in improving QOL at short term (1 month to 6 months), but it was not statistically significant. Hence there is no difference in improvement of QOL between the PRP and steroid groups from 1 month to 6 months.

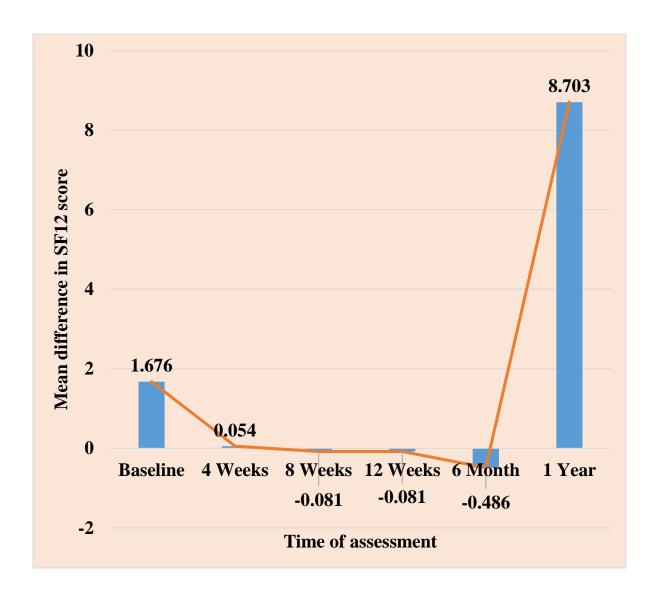


Figure 31: Combo diagram showing differences in SF-12 score between the study groups before and after the procedure at follow-up by Independent T test.

DISCUSSION

All patients who were diagnosed with DFJS between September 2022-May 2023, met the inclusion criteria and were admitted to the Orthopaedics Department at R.L. Jalappa Hospital, Kolar were included in the study. A computer online random generator software was used to randomly divide the samples of 74 patients into two groups, with 37 samples in each group. Group A patients were treated with IA PRP injection, while Group B patients received IA CS injection. Patients were monitored after 4 weeks, 8 weeks, 12 weeks, 6 months & at 1 year after receiving an IA injection. During the follow-up, each patient was evaluated using several assessment tools, including the VAS score, PPI score, MODI score, RMQ score and SF-12 score.

Comparison of baseline characteristics of the study groups

Mean age of the DFJS patients in PRP group was 50.81 ± 7.7 years and the average age of the DFJS patients in steroid group was 48.86 ± 10.7 years. About 56.8% of the DFJS patients were male in PRP group, and the remaining 43.2% were female. Similarly, 48.6% of the DFJS patients were male in steroid group, and the remaining 51.4% were female.

Wu et al. conducted prospective study to weigh up the efficacy of IA injections of PRP and steroid in the treatment of LFJS. ⁵⁰ In the PRP group, the

average age of DFJS patients was 52.91 ± 7.6 years, while in the steroid group, it was 52.78 ± 7.25 years. In the PRP group, 43.48% were males, while females accounted for 52.9%. Just as in the steroid group, women made up 60.8% of the LFJS patients and men 39.1%.

Bise et al. conducted a study where 60 patients were evaluated for pain at baseline and function at 6 weeks post-treatment using the ODI and NRS, respectively. ⁶⁶ The average age of the steroid group was fifty, whereas the average age of the PRP group was sixty-nine. In the steroid group, over 63% of participants were men, while in the PRP group, about 60% were men.

For his retrospective study, Demirci compared the effectiveness of PRP therapy with that of CS treatment in 62 individuals suffering from radicular pain. ⁶⁷ With an average age of 49.6 years, the PRP group outlasted the steroid group by a wide margin. Among the steroid group, 45.1% were men, while among the PRP group, 25.8% were men.

Comparative results in VAS score with similar studies (PRP injection group)

In the present study, the pain score was 6.65 prior to the PRP injection, but it decreased to 5.05 after 4 weeks and to 3.92 at 8 weeks. Subsequently, the pain score showed decline at three months (2.89) and a significant decline at six months (1.84) and 1 year (1.05), all of which occurred after the PRP injection.

In the treatment of DFJS patients, there is a consistent reduction in pain score after PRP injection.

Comparable findings were noted in study by Bise et al⁶⁶, Mohamed et al⁶⁹ and Wu et al⁶⁸. Partially supportive results were observed in the study by Ruiz-Lopez et al⁷⁰ and Kotb et al². In all these studies there is a consistent reduction in pain score after PRP injection.

Table 20: Comparison of VAS score in PRP injection group with similar studies

Authors	Mean VAS score						
71441015	Baseline	4 weeks	3 months	6 months	1 year		
Present study	6.65	5.05	2.89	1.84	1.05		
Kotb et al ²	8	-	5.73	-	-		
Wu et al ⁶⁸	7.05	4.89	2.63	-	-		
Bise et al ⁶⁶	6.3*	4#	-	-	-		
Mohamed et al ⁶⁹	6.7	-	3.5	-	-		
Ruiz-Lopez et al ⁷⁰	7.48	5.20	5.70	6.08	-		

^{*} Numerical rating scale used, # at 6 weeks

Comparative results in VAS score with similar studies (Steroid injection group)

In the present study, the pain score was 6.76 prior to the steroid injection, but it decreased to 4.35 after 4 weeks and to 3.27 at 8 weeks. The pain score

reduced at three months (2.32), and a significant decline at six months (1.3) and finally pain score increased at 1 year (2.65), all of which occurred after the steroid injection. In the treatment of DFJS patients, there is a consistent reduction in pain score after steroid injection.

Table 21: Comparison of VAS score in Steroid injection group with similar studies

Authors	Mean VAS score						
714411015	Baseline	4 weeks	3 months	6 months	1 year		
Present study	6.76	4.35	2.32	1.3	2.65		
Kotb et al ²	8.07	-	5.73	-	-		
McCormick et al ⁷¹	6.2*	3.2*	4.1*	4.1*	4.8*		
Bise et al ⁶⁶	5.2*	3.4#	-	-	-		
Mohamed et al ⁶⁹	6.7	-	3	-	-		
Ruiz-Lopez et al ⁷⁰	7.18	4.40	6.28	7.53	-		

^{*} Numerical rating scale used, # at 6 weeks

Comparable findings were noted in study by Mohamed et al⁶⁹ and McCormick et al⁷¹. Partially supportive results were observed in the study by Bise et al⁶⁶, Ruiz-Lopez et al⁷⁰ and Kotb et al². In all these studies there is a consistent reduction in pain score after steroid injection.

Comparative results in MODI score with similar studies (PRP injection group)

In the present study, the disability score was 54.97 prior to the PRP injection, but it decreased to 50.14 after 4 weeks and to 44.49 at 8 weeks. Subsequently, the disability score dropped at three months (38.38), with a significant decline at six months (29.92) and 1 year (21.19), all of which occurred after the PRP injection. In the treatment of DFJS patients, there is a consistent reduction in disability score after PRP injection.

Table 22: Comparison of disability score in PRP injection group with similar studies

Authors	Mean MODI score						
	Baseline	4 weeks	3 months	6 months	1 year		
Present study	54.97	50.14	38.38	29.92	21.19		
Kotb et al ²	58.13	-	47.60	-	-		
Wu et al ⁶⁸	54.32*	27.79*	26.32*	-	-		
Bise et al ⁶⁶	29.8*	23#	-	-	-		
Demirci ⁶⁷	63.7*	33.9*	-	32.6*	-		

^{*} ODI was used, # at 6 weeks

Comparable findings were noted in study by Wu et al⁶⁸ and Kotb et al². Partially supportive results were observed in the study by Demirci ⁶⁷ and Bise et

al⁶⁶. In all these studies there is a consistent reduction in disability score after autologous PRP injection.

Comparative results in MODI score with similar studies (Steroid injection group)

In this study, the disability score was 55.97 prior to the steroid injection, but it decreased to 49.57 after 4 weeks and to 43.62 at 8 weeks. A decline in the disability score was noted at three months (37.08), further reduced at six months (27.51) and finally disability score increased at 1 year (30.86), all of which occurred after the steroid injection. In the treatment of DFJS patients, there is a consistent reduction in disability score after steroid injection. Partially supportive results were observed in the study by Kotb et al², McCormick et al⁷¹, Demirci ⁶⁷ and Bise et al⁶⁶. In all these studies there is a consistent reduction in disability score after IA steroid injection. The difference in mean disability score was due to original version of ODI score was used and these studies was done in different settings.

Table 23: Comparison of disability score in steroid injection group with similar studies

Authors	Mean MODI score						
	Baseline	4 weeks	3 months	6 months	1 year		
Present study	55.97	49.57	37.08	27.51	30.86		
Kotb et al ²	61.6	-	50.13	-	-		
McCormick et	19.5*	11.6*	11.7*	10.6*	12.4*		
Bise et al ⁶⁶	30*	20#	-	-	-		
Demirci ⁶⁷	62.1*	30.2*	-	32.8*	-		

^{*}ODI was used, # at 6 weeks

The current study demonstrates that both groups' rates of impairment have notably decreased. PRP was better than steroid in reducing perceived disability (MODI) at long term (1 year), and it was statistically significant. Steroid is better than PRP in reducing perceived disability in short term (1 month to 6 months), but it was not significant. Hence there is no difference in improvement of disability between the PRP and steroid groups from 1 month to 6 months. The disability score corresponds to variation in VAS score. As the pain score decreases there is notable improvement in functional ability of the study patients with DFJS.

Comparative results in RMQ score with similar studies (PRP injection group)

The pain related disability score (RMQ) was 11.03 prior to the PRP injection, but it decreased to 8.86 after 4 weeks and to 6.86 at 8 weeks. Subsequently, the disability score showed decline at three months (5.11), and a significant decline at six months (3.32) and 1 year (2.08), all of which occurred after the PRP injection. In the treatment of DFJS patients, there is a consistent reduction in pain related disability score after PRP injection.

Table 24: Comparison of pain related disability score in PRP injection group with similar studies

Authors	Mean RMQ score							
	Baseline	4 weeks	3 months	6 months	1 year			
Present study	11.03	8.86	5.11	3.32	2.08			
Kotb et al ²	19.33	-	14.27	-	-			
Akeda et al ⁵⁵	12.6	5.1	-	3.6	2.8			
Wu et al ⁵⁰	17.2	-	-	8.2	-			

Comparable findings were noted in study by Akeda et al⁵⁵. Partially supportive results were observed in the study by Kotb et al² and Wu et al⁵⁰. In all these studies there is a consistent reduction in pain related disability score after autologous PRP injection.

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Comparative results in RMQ score with similar studies (Steroid injection group)

The pain related disability score (RMQ) was 10.97 prior to the steroid injection, but it decreased to 7.92 after 4 weeks and to 6.27 at 8 weeks. Significant decline was noted in the disability score at three months (4.51), at six months (2.54) and then it increased to 1 year (3.97), all of which was noted after the steroid injection. There is a consistent reduction in RMQ pain related disability score after steroid injection.

Table 25: Comparison of pain related disability score in steroid injection group with similar studies

Authors	Mean RMQ score							
	Baseline	4 weeks	3 months	6 months	1 year			
Present study	10.97	7.92	4.51	2.54	3.97			
Kotb et al ²	19.13	-	15.20	-	-			
Wu et al ⁵⁰	17.3	-	-	13.6	-			

Partially supportive results were observed in the study by Kotb et al² and Wu et al⁵⁰. In all these studies there is a consistent reduction in pain related disability score after steroid injection.

There is a significant decrease in self-rated physical disability in both the groups. PRP is better than steroid in reducing self-rated physical disability (RMQ) at long term (6 months and 1 year), whereas steroid is better than PRP in reducing self-rated physical disability at 4 weeks. Steroid is better than PRP in reducing self-rated physical disability at 8 and 12 weeks but it was not statistically relevant and no difference was noted between both groups. The pain related disability score corresponds to variation in VAS score, and it didn't differ between the study groups. The study patients with DFJS show a significant increase in their functional abilities when their pain score drops.

Comparative results in SF-12 score with similar studies (PRP injection group)

The mean SF-12 score was 50.76 prior to the PRP injection, but it improved to 55.35 after 4 weeks and to 60.11 at 8 weeks. The QOL score showed an additional increase at three months (64.97), and a significant incline at six months (70.54) and at 1 year (75.35), all of which occurred after injecting PRP. Consistent improvement in QOL (SF-12 score) was noted after PRP injection. Comparable values were noted in the analysis by Kotb et al. in which the quality of life was improved after PRP injection.² Similar observation was made in which there was notable increase in the physical composite score of SF-12 in the study by Singla et al.⁷²

Table 26: Comparison of SF-12 score in PRP injection group with similar studies

Authors	Mean SF 12 score							
	Baseline	4 weeks	3 months	6 months	1 year			
Present study	6.65	5.05	2.89	1.84	1.05			
Kotb et al ²	8	-	5.73	-	-			
Singla et al ⁷²	30	-	49	-	-			

^{*}Physical composite score

Comparative results in SF-12 score with similar studies (Steroid injection group)

The mean SF-12 score was 49.08 prior to the steroid injection, but it increased to 55.3 after 4 weeks and to 60.19 at 8 weeks. Subsequently, the QOL improved at three months (65.05), with a significant incline at six months (71.03) and finally SF-12 score decreased at 1 year (66.65), all of which occurred after the steroid injection. In the treatment of DFJS patients, there is a consistent increase in SF-12 score after steroid injection.

Comparable results were noted in the study by Kotb et al. in which the quality of life was improved after steroid injection.² Similar observation was made in which there was significant increase in score of SF-12 in the study by Singla et al⁷².

Table 27: Comparison of SF-12 score in Steroid injection group with similar studies.

Authors	Mean SF 12 score				
	Baseline	4 weeks	3 months	6 months	1 year
Present study	6.65	5.05	2.89	1.84	1.05
Kotb et al ²	8	-	5.73	-	-
Singla et al ⁷²	29*	-	37*	-	-

^{*}Physical composite score

There is significant improvement in health-related QOL for both the groups. PRP was better than steroid in improving health-related QOL (SF-12) at long term (1 year), and it was statistically significant. Steroid was better than PRP in improving health-related QOL in the short term (1 month to 6 months), but it was not relevant. Thus, there is no variation in the enhancement of health-related quality of life between the PRP and steroid groups from 1 month to 6 months.

There appears to be a gold standard for comparing novel injectable therapies, and one of the most used medications for interventional LFJ injection treatment is CS, with or without LA. LAs only provide short-term relief from symptoms, according to most specialists. In contrast, LFJ CS injections are believed to be justified in treating inflammation caused by OA. ⁷³ Nevertheless, the precise way in which intra-articular steroid injection works remains a mystery.

According to Pneumaticos et al., 87% of patients with anomalies in their FJ reported less pain one month after receiving injections of CS and local anaesthetics; however, only 53% reported the similar outcomes six months later. Based on these data, the immediate impacts of the injection, whether with or without local anaesthesia, are more favourable compared to its long-term effects. Multiple systematic studies have demonstrated that intra-articular CS injection can provide temporary relief from pain and enhance functionality in LFJs. However, there is limited data supporting the long-term effectiveness of this treatment in alleviating discomfort. A3,75

A study was carried out in India by Singh et al. in 2023 that evaluated 60 patients of back pain. Injectable autologous PRP was determined to be the best novel injectable preparation for treating LFJS via IA injection. After 6 months of follow-up, it was found that both steroid injections and PRP injection were safe and effective for the treatment of LFJS. On the other hand, autologous PRP has the potential to be more effective for a longer period of time. ⁷⁶

PRP usually obtained by a two-step centrifugation process can help alleviate pain in cases of LFJS. PRP injections were determined to be a risk-free substitute for LA and CS, with no ill effects whatsoever. After six months, the CS group's success rates and satisfaction levels declined, compared to the beginning. In contrast, the PRP group maintained their improvement throughout the research.⁵⁰

In a 2022 trial, 30 Egyptian patients with LFJ illness were randomly assigned to either a PRP or CS injection group, according to the researchers Kotb et al. ² All the indicated parameters were significantly improved in both groups during the 3-month follow-up. The results of MRI synovitis grade in the lumbar region were improved overall with PRP injections, in contrast to CS injections. According to their research, PRP has the potential to be a more effective and longer-lasting treatment option.

CONCLUSION

The study findings demonstrated that both options were successful in alleviating pain and functional impairment. However, PRP exhibited greater efficacy compared to the steroid. The PRP group had a more pronounced and enduring decrease in pain intensity and enhancement in functional impairment compared to the steroid group. Patients in steroid group had a significant relief in the short term, but their effectiveness declined later.

Autologous PRP is a very suitable, novel injectable medication for administering intra-articular injections to address LFJ dysfunction. After a year of follow-up, both PRP injection and LA/CS injection were shown to be efficacious, uncomplicated, and sufficiently safe for managing LFJS. Both groups saw a substantial reduction in pain and impairment, which was assessed using the VAS, MODI, RMQ, and PPI scores. Both groups experienced a notable enhancement in health-related QOL, based on SF-12 scores. Nevertheless, autologous PRP may be a more advantageous therapeutic choice for longer-lasting effectiveness.

To enhance the credibility of these findings, future research should consider doing a placebo-controlled trial with a bigger sample size and more stringent patient selection criteria.

LIMITATIONS

- This trial was conducted without a placebo-controlled group for comparison with the PRP plus steroid group.
- Given the limited number of participants and the restriction of the research to a specific site, it is plausible that the findings may not be applicable to the entire community.
- The potential complications of LFJ injection may come from the puncture process, and the potential concerns related to the administration of PRP, and steroid were not taken into account.
- We did not do a preliminary diagnostic block to ascertain patient eligibility. Therefore, our confirmation of diagnosis and selection of patients were solely reliant on a thorough clinical examination.
- We exclusively assessed clinical parameters utilizing the VAS, MODI, and SF-12 systems, which largely gauge pain and disability. Additional laboratory parameters indicating the impact of treatment on the illness process were not evaluated.

SUMMARY

Prior studies have demonstrated that injecting the FJs with medication directly into the joint space, known as intra-articular FJ injection, can be beneficial for relieving pain caused by FJ dysfunction. As a result, this approach is frequently used for this specific purpose. The purpose of this observational study was to compare the functional effects of a single IA CS injection with a single dosage of autologous PRP injection. The study also strived to evaluate the short-term and long-term impact of both treatments in the management of DFJS.

All consecutive patients who were diagnosed with DFJS between September 2022 and May 2023 and were admitted to the Orthopaedics department of the R.L. Jalappa hospital, Kolar. A computer online random generator software was utilised to randomly divide the samples of 74 patients into two groups, with 37 samples in each group. Group A patients received IA PRP injection, while Group B patients received IA CS injection. Patients were monitored after 4 weeks, 8 weeks, 12 weeks, 6 months & 1 year after receiving an IA injection.

Mean age of the DFJS patients in PRP group was 50.81 ± 7.7 years and the mean age of the DFJS patients in steroid group was 48.86 ± 10.7 years. About 56.8% of the DFJS patients were male in PRP group, and the remaining 43.2% were female. Similarly, 48.6% of the DFJS patients were male in steroid group,

and the remaining 51.4% were female. There is a significant decrease in pain in both the groups. PRP is better than steroid in reducing perceived pain (VAS) in the long term (1 year), whereas steroid is better than PRP in reducing perceived pain at short term (1 month to 6 months).

In both groups, there has been a notable decline in impairment. PRP was better than steroid in reducing perceived disability (MODI) at long term (1 year), and it was statistically significant. Steroid is better than PRP in reducing perceived disability in short term (1 month to 6 months), but it was not statistically relevant. Hence there is no difference in improvement of disability between the PRP and steroid groups from 1 month to 6 months.

There is a significant improvement in self-rated physical disability in both the groups. PRP is better than steroid in reducing self-rated physical disability (RMQ) at long term (6 months and 1 year), whereas steroid is better than PRP in reducing self-rated physical disability at 4 weeks. Steroid is better than PRP in reducing self-rated physical disability at 8 and 12 weeks though not statistically relevant and there was no difference among both groups.

PRP is better than steroid in reducing perceived pain (PPI) at long term (1 year), whereas steroid is better than PRP in reducing perceived pain at short term (4, 8 and 12 weeks). Steroid was better than PRP in reducing self-rated physical disability at 6 months, but it was not statistically relevant and there was no difference between the two groups.

Significant improvement was noted in health-related QOL for both the groups. PRP was better than steroid in improving health-related QOL (SF-12 score) at long term (1 year), and it was statistically significant. Steroid was better than PRP in improving health-related QOL in the short term (1 month to 6 months), but it was not relevant statistically. Hence there is no difference in improvement of health-related QOL between the PRP and steroid groups from 1 month to 6 months.

An optimal novel injectable medication for the treatment of LFJ dysfunction would be autologous PRP. Following a one-year period of monitoring, it was determined that both steroid injection and PRP injection were safe, uncomplicated, and effective in treating LFJS. There was a significant reduce in pain and disability in both groups and it was measured by VAS, MODI, RMQ and PPI questionnaire. There was a significant improvement in health-related QOL for both the groups as measured by SF-12. Nevertheless, autologous PRP may offer a more effective therapeutic option in terms of longer-lasting effectiveness.

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SRI DEVARAJ URS ACADEMY OF HIGHER EDUCATION AND RESEARCH, TAMAKA, KOLAR - 563101.

PATIENT INFORMATION SHEET

STUDY TITLE: "A PROSPECTIVE COMPARATIVE STUDY OF FLUOROSCOPIC GUIDED SINGLE INTRA-ARTICULAR INJECTION OF AUTOLOGOUS PLATELET RICH PLASMA VERSUS CORTICOSTEROID IN DEGENERATIVE FACET JOINT SYNDROME – A RANDOMISED CONTROL TRIAL"

Study location: R L Jalappa Hospital and Research Centre attached to Sri Devaraj Urs Medical College, Tamaka, Kolar.

Details:

Patients aged between 35 and 80 years diagnosed having degenerative lumbar facet joint syndrome who visit to the Emergency department or department of Orthopaedics at R.L.Jalappa Hospital and Research Centre, attached to Sri Devaraj Urs Medical College, Tamaka, Kolar will be included in this study in one of the two groups.

Patients in this study will have to undergo routine blood investigations (CBC, HIV, HCV& HBsAG), MRI lumbosacral spine and X-ray of lumbosacral spine –AP and Lateral views.

Please read the following information and discuss with your family members. You can ask any question regarding the study. If you agree to participate in the study, we will collect information (as per proforma) from you or a person responsible for you or both. Relevant history will be taken. This information collected will be used only for dissertation and publication. The cost required for conducting this study shall be borne entirely by the Doctor conducting this study.

All information collected from you will be kept confidential and will not be disclosed to any outsider. Your identity will not be revealed. This study has been reviewed by the Institutional Ethics Committee and you are free to contact the member of the Institutional Ethics Committee. There is no compulsion to agree to this study. The care you will get will not change if you don't wish to participate. You are required to sign/ provide thumb impression

only if you voluntarily agree to participate in this study.

CONFIDENTIALITY

Your medical information will be kept confidential by the study doctor and staff and will not be made publicly available. Your original records may be reviewed by your doctor or ethics review board. For further information/ clarification please contact

Department Of Orthopaedics,

Dr. Aryadev Jayakrishnan,

SDUMC, Kolar

CONTACT NO: 8197964568

ಶ್ರೀ ದೇವರಾಜ್ ಅರ್ಸ್ ಉನ್ನತ ಶಿಕ್ಷಣ ಮತ್ತು ಸಂಶೋಧನೆ ಅಕಾಡೆಮಿ, ತಮಕ್ಕ ಕೋಲಾರ - 563101.

ರೋಗಿಯ ಮಾಹಿತಿ ಹಾಳೆ

ಅಧ್ಯಯನದ ಶೀರ್ಷಿಕೆ: "ಸ್ವಯಂಚಾಲಿತ ಪ್ಲೇಟ್ ಲೆಟ್ ಸಮೃದ್ಧ ಪ್ಲಾಸ್ಮಾದ ಫ್ಲೋರೋಸ್ಕೊಪಿಕ್ ಗೈಡೆಡ್ ಸಿಂಗಲ್ ಇಂಟ್ರಾ ಆರ್ಟಿಕ್ಯುಲರ್ ಇಂಜೆಕ್ಷನ್ ನಿರೀಕ್ಷಿತ ತುಲನಾತ್ಮಕ ಅಧ್ಯಯನ ವರ್ಸೆಸ್ ಕ್ಷೀಣಗೊಳ್ಳುವ ಮುಖವಾಗಬಹುದಾದ ಜಂಟಿ ಸಿಂಡ್ರೋಮ್ - ಎ ರಾಂಡಮೈಸ್ಡ್ ನಿಯಂತ್ರಿತ ಪ್ರಯೋಗ"

ಅಧ್ಯಯನದ ಸ್ಥಳ: ಆರ್ ಎಲ್ ಜಾಲಪ್ಪ ಆಸ್ಪತ್ರೆ ಮತ್ತು ಸಂಶೋಧನಾ ಕೇಂದ್ರವು ಶ್ರೀ ದೇವರಾಜ್ ಅರಸ್ ವೈದ್ಯಕೀಯ ಕಾಲೇಜು, ಟಮಕ್ಕ ಕೋಲಾರ.

ವಿವರಗಳು-

ಕೋಲಾರದ ತಮಕ್ಕ ಶ್ರೀ ದೇವರಾಜ್ ಯುಆರ್ಎಸ್ ವೈದ್ಯಕೀಯ ಕಾಲೇಜು, ಆರ್.ಎಲ್.ಜಾಲಪ್ಪ ಆಸ್ಪತ್ರೆ ಮತ್ತು ಸಂಶೋಧನಾ ಕೇಂದ್ರದ ತುರ್ತು ವಿಭಾಗದಲ್ಲಿ ಅಥವಾ ಮೂಳೆಚಿಕಿತ್ಸಾ ವಿಭಾಗಳಲ್ಲಿ ಭೇಟಿ ನೀಡುವ 35 ಮತ್ತು 80 ವರ್ಷಗಳ ಮಧ್ಯವಿರುವ ವಯಸ್ಸಿನ ರೋಗಿಗಳಲ್ಲಿ ಕ್ಷೀಣಗೊಳ್ಳುವ ಮುಖವಾಗಬಹುದಾದ ಜಂಟಿ ಸಿಂಡ್ರೋಮ್ ರೋಗನಿರ್ಣಯವನ್ನು ಮಾಡಲಾಗಿರುತ್ತದೆ, ಇವರನ್ನು ಈ ಅಧ್ಯಯನದಲ್ಲಿರುವ ಎರಡು ಗುಂಪುಗಳಲ್ಲಿ ಒಂದರಲ್ಲಿ ಸೇರಿಸಲಾಗುತ್ತದೆ.

ಈ ಅಧ್ಯಯನದಲ್ಲಿ ರೋಗಿಗಳು ವಾಡಿಕೆಯ ಪ್ರಕಾರ ನಿಯತ ಕಾರ್ಯಕ್ರಮದಲ್ಲಿ ರಕ್ತ ಪರೀಕ್ಷೆಗೆ ಒಳಗಾಗಬೇಕಾಗುತ್ತದೆ (ಸಿಬಿಸಿ, ಆರ್ಎಫ್ಟಿ, ಸೀರಮ್ ಎಲೆಕ್ಟ್ರೋಲೈಟ್ ಗಳು, ರಕ್ತದ ಗುಂಪಿನ ಪರೀಕ್ಷೆಗಳು, ಎಚ್ಐವಿ ಮತ್ತು ಎಚ್ಬಿಎಸ್ಎಜಿ), ಎದೆಯ ಕ್ಷ ಕಿರಣ, ಇಸಿಜಿ, ಎಂಆರ್ಐ ಲುಂಬೊಸ್ಯಾಕರಲ್ ಬೆನ್ನುಮೂಳೆಯ ಮತ್ತು ಲುಂಬೊಸ್ಯಾಕರಲ್ ಬೆನ್ನೆಲುಬಿನ ಎಕ್ಸ್-ರೇ - ಎಪಿ ಮತ್ತು ಲ್ಯಾಟರಲ್ ವೀಕ್ಷಣೆಗಳು ಮುಂತಾದವುಗಳು

ದಯವಿಟ್ಟು ಕೆಳಗೆ ನೀಡಲಾಗಿರುವ ಮಾಹಿತಿಯನ್ನು ಓದಿ ಮತ್ತು ನಿಮ್ಮ ಕುಟುಂಬದ ಸದಸ್ಯರೊಂದಿಗೆ ಚರ್ಚಿಸಿ. ಈ ಅಧ್ಯಯನಕ್ಕೆ ಸಂಬಂಧಿಸಿದಂತೆ ನೀವು ಯಾವುದೇ ಪ್ರಶ್ನೆಯನ್ನು ಕೇಳಬಹುದು.ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸಲು ನೀವು ಒಪ್ಪಿದರೇ, (ಪ್ರೊಫಾರ್ಮಾ ಪ್ರಕಾರ) ನಾವು ನಿಮ್ಮಿಂದ ಅಥವಾ ನಿಮಗೆ ಜವಾಬ್ದಾರಿಯಾಗಿರುವ ವ್ಯಕ್ತಿಯಿಂದ ಅಥವಾ ಇಬ್ಬರಿಂದ ಮಾಹಿತಿಯನ್ನು ಸಂಗ್ರಹಿಸುತ್ತೇವೆ.

ನಿಮ್ಮಿಂದ ಸಂಗ್ರಹಿಸಲಾಗಿರುವ ಎಲ್ಲಾ ಮಾಹಿತಿಯನ್ನು ಗೌಪ್ಯವಾಗಿ ಇಡಲಾಗುತ್ತದೆ ಹೊರಗಿನವರಲ್ಲಿ ವಿವರಗಳಿರುವ ಮತ್ತು ಯಾರಿಗೂ ಈ ಮಾಹಿತಿಯನ್ನುಬಹಿರಂಗಪಡಿಸಲಾಗುವುದಿಲ್ಲ. ನಿಮ್ಮ ವ್ಯಕ್ತಿತ್ವದ ಗುರುತನ್ನು ಬಹಿರಂಗಪಡಿಸುವುದಿಲ್ಲ. ಈ ಅಧ್ಯಯನವನ್ನು ಸಾಂಸ್ಥಿಕ ನೀತಿಶಾಸ್ಸ್ರ ಸಮಿತಿಯು ಪರಿಶೀಲಿಸುತ್ತದೆ. ಮತ್ತು ನೀವು ಯಾವ ಸಮಯದಲಿ ಆದರೂ ಸಾಂಸ್ಥಿಕ ನೈತಿಕ ಸವಿತಿಯ ಸದಸ್ಯರನ್ನು ಸಂಪರ್ಕಿಸಬಹುದು, ಅದಕ್ಕೆ ಯಾರಿಂದಲೂ ಆಪೇಕ್ಷಣೆ ಇರುವುದಿಲ್ಲ. ಈ ಅಧ್ಯಯನವನ್ನು ಒಪ್ಪಿಕೊಳ್ಳಲು ಯಾರಿಂದಲೂ ಯಾವುದೇ ಒತ್ತಾಯವಿರುವುದಿಲ್ಲ. ನೀವು ಭಾಗವಹಿಸಲು ಬಯಸದಿದ್ದರೆ ನೀವು ಪಡೆಯುವ ವೈದ್ಯಕೀಯ ಕಾಳಜಿಯು ಬದಲಾಗುವುದಿಲ್ಲ. ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸಲು ಸಮ್ಮತಿಸಿದರೆ ಸ್ವಯಂಪ್ರೇರಣೆಯಿಂದ ನೀವು ಸಹಿ ನೀವು ಮಾತ್ರ ಮಾಡಬೇಕಾಗಿರುತ್ತದೆ/ಹೆಬೈರಳಿನ ಗುರುತನ್ನು ಒದಗಿಸಬೇಕಾಗುತ್ತದೆ.

ಗೌಪ್ಯತೆ.

ನಿಮ್ಮ ವೈದ್ಯಕೀಯ ಮಾಹಿತಿಯ ವಿವರಗಳನ್ನು ಅಧ್ಯಯನದ ವೈದ್ಯರು ಮತ್ತು ಸಿಬ್ಬಂದಿ ಗೌಪ್ಯವಾಗಿಡುತ್ತಾರೆ ಮತ್ತು ಸಾರ್ವಜನಿಕವಾಗಿ ಲಭ್ಯವಾಗುವಂತೆ ಮಾಡಲಾಗುವುದಿಲ್ಲ. ನಿಮ್ಮ ಮೂಲ ದಾಖಲೆಗಳನ್ನು ನಿಮ್ಮ ವೈದ್ಯರು ಅಥವಾ ಎಥಿಕ್ಸ್ ರಿವ್ಯೂ ಬೋರ್ಡ್ ಪರಿಶೀಲಿಸಬಹುದಾಗಿರುತ್ತದೆ. ಹೆಚ್ಚಿನ ಮಾಹಿತಿಯನ್ನು ಪಡೆಯಲು / ಸ್ಪಷ್ಟೀಕರಣಕ್ಕಾಗಿ ದಯವಿಟ್ಟು ಇವರನ್ನು ಸಂಪರ್ಕಿಸಿ

ಡಾ. ಆರ್ಯದೇವ್ ಜಯಕ್ರಿಷ್ಣನ್ ಆರ್ಥೋಪೆಡಿಕ್ಸ್ ವಿಭಾಗ್ಯ, ಎಸ್ ಡಿ ಯು ಎಮ್ ಸಿ. ಕೋಲಾರ, ಸಂಪರ್ಕಿಸಬಹುದಾದ ಫೋನ್ ಸಂಖ್ಯೆ. 8197964568

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WRITTEN INFORMED CONSENT FORM

I Mr./Mrs have been explained in my own understandable language, that I will
be included in a study which is "A PROSPECTIVE COMPARATIVE STUDY OF
FLUOROSCOPIC GUIDED SINGLE INTRAARTICULAR INJECTION OF
AUTOLOGOUS PLATELET RICH PLASMA VERSUS CORTICOSTEROID IN
DEGENERATIVE FACET JOINT SYNDROME - A RANDOMISED CONTROL
TRIAL"
I have been explained that my clinical findings, investigations, postoperative findings will be
assessed and documented for study purpose.
I have been explained my menticipation in this study is entirely velyntomy and I can withdraw
I have been explained my participation in this study is entirely voluntary, and I can withdraw
from the study any time and this will not affect my relation with my doctor or the treatment for my ailment.
for my annient.
I have been explained about the interventions needed possible benefits and adversities due to
interventions, in my own understandable language.
I have been explained that the cost required to conduct this study shall be borne entirely by
the doctor conducting this study.
I have understood that all my details found during the study are kept confidential and while

publishing or sharing of the findings, my details will be masked.

I have the principal investigator mobile number for enquiries.
I/We the patient and the patient attenders hold the full responsibility for the procedure and the further consequences. I will not hold any treating doctor, nursing staff and hospital management for any untoward consequences.
I in my sound mind give full consent to be added in the part of this study.
Signature of the patient:
Name:
Signature of the witness: Name:
Relation to patient:
Place:

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<u>ಲಿಖಿತ ಮಾಹಿತಿ ನೀಡುವ ಒಪ್ಪಿಗೆಯ ನಮೂನೆ</u>

ಶ್ರೀ/ಶ್ರೀಮತಿ. _____ ಆದ ನನ್ನನ್ನು ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಸೇರಿಸಲಾಗಿದೆ ಎಂದು ನನಗೆ ಅರ್ಥವಾಗುವಂತಹ ನನ್ನ ಬಾಷೆಯಲ್ಲಿ ವಿವರಿಸಲಾಗಿದೆ, ಆ ಅಧ್ಯಯನವೇನಂದರೇ, "ಸ್ವಯಂಚಾಲಿತ ಪ್ಲೇಟ್ ಲೆಟ್ ಸಮೃದ್ಧ ಪ್ಲಾಸ್ಮಾದ ಫ್ಲೋರೋಸ್ಕೋಪಿಕ್ ಗೈಡೆಡ್ ಸಿಂಗಲ್ ಇಂಟ್ರಾ ಆರ್ಟಿಕ್ಯುಲರ್ ಇಂಜೆಕ್ಷನ್ ನಿರೀಕ್ಷಿತ ತುಲನಾತ್ಮಕ ಅಧ್ಯಯನ ವರ್ಸೆಸ್ ಕ್ಷೀಣಗೊಳ್ಳುವ ಮುಖವಾಗಬಹುದಾದ ಜಂಟಿ ಸಿಂಡ್ರೋಮ್ - ಎ ರಾಂಡಮೈಸ್ಡ್ ನಿಯಂತ್ರಿತ ಪ್ರಯೋಗ"

ನನಗೆ ಸಂಭದಿಸಿದ ಕ್ಲಿನಿಕಲ್ ಸಂಶೋಧನೆಗಳು, ಪರಿಶೋದನೆಗಳು, ಶಸ್ತ್ರಚಿಕಿತ್ಸೆಯ ನಂತರದ ಸಂಶೋಧನೆಗಳನ್ನು ಮೌಲ್ಯಮಾಪನ ಮಾಡಲಾಗುತ್ತದೆ ಎಂದು ಮತ್ತು ಅಧ್ಯಯನ ಉದ್ಯೇಶಕ್ಕಾಗಿ ಮಾತ್ರ ದಾಖಲಿಸಲಾಗುತ್ತದೆ ಎಂದು ನನಗೆ ವಿವರಿಸಲಾಗಿದೆ.

ಈ ಅಧ್ಯಯನದಲ್ಲಿ ನನ್ನ ಭಾಗವಹಿಸುವಿಕೆಯು ಸಂಪೂರ್ಣವಾಗಿ ಸ್ವಯಂಪ್ರೇರಿತವಾಗಿದೆ ಎಂದು, ಮತ್ತು ನಾನು ಯಾವುದೇ ಸಮಯದಲ್ಲಿ ಆದರೂ ಈ ಅಧ್ಯಯನದಿಂದ ಹಿಂದೆ ಸರಿಯಬಹುದು ಎಂದೂ ಮತ್ತು ಈ ಅಧ್ಯಯನ ನನ್ನ ವೈದ್ಯರೊಂದಿಗಿನ ನನ್ನ ಸಂಬಂಧ ಅಥವಾ ನನ್ನ ಕಾಯಿಲೆಯ ಚಿಕಿತ್ಸೆಯ ಮೇಲೆ ಪರಿಣಾಮ ಬೀರುವುದಿಲ್ಲ ಎಂದೂ ನನಗೆ ವಿವರಿಸಲಾಗಿದೆ.

ಅಗತ್ಯವಿರುವ ಮಧ್ಯಸ್ಥಿಕೆಗಳ ಬಗ್ಗೆ ನನಗೆ ಅರ್ಥವಾಗುವ ನನ್ನ ಸ್ವಂತ ಬಾಷೆಯಲ್ಲಿ ಮಧ್ಯಸ್ಥಿಕೆಗಳಿಂದ ಆಗುವಂತಹ ಸಂಭವನೀಯ ಪ್ರಯೋಜನಗಳು ಮತ್ತು ಪ್ರತಿಕೂಲತೆಗಳ ಬಗ್ಗೆ ನನಗೆ ವಿವರಿಸಲಾಗಿದೆ.

ಈ ಅಧ್ಯಯನವನ್ನು ನಡೆಸಲು ಅಗತ್ಯವಿರುವ ಖರ್ಚಿನ ವೆಚ್ಚವನ್ನು ಈ ಅಧ್ಯಯನವನ್ನು ನಡೆಸುವ ವೈದ್ಯರೇ ಸಂಪೂರ್ಣವಾಗಿ ಭರಿಸುತ್ತಾರೆ ಎಂದು ನನಗೆ ವಿವರಿಸಲಾಗಿದೆ.

ಅಧ್ಯಯನದ ಸಮಯದಲ್ಲಿ ಪತ್ತೆಯಾದ ನನ್ನ ಎಲ್ಲಾ ವಿವರಗಳನ್ನು ಗೌಪ್ಯವಾಗಿಡಲಾಗುತ್ತದೆ ಮತ್ತು ಸಂಶೋಧನೆಗಳನ್ನು ಪ್ರಕಟಿಸುವಾಗ ಅಥವಾ ಹಂಚಿಕೊಳ್ಳುವಾಗ, ನನ್ನ ವಿವರಗಳನ್ನು ಮರೆಮಾಚಲಾಗುತ್ತದೆ ಎಂದು ನಾನು ಅರ್ಥಮಾಡಿಕೊಂಡಿದ್ದೇನೆ.

ವಿವರಣೆಯನ್ನು ಪಡೆಯಲು ನಾನು ಪ್ರಧಾನ ತನಿಖಾಧಿಕಾರಿಯ ಮೊಬೈಲ್ ಸಂಖ್ಯೆಯನ್ನು ಹೊಂದಿದ್ದೇನೆ. ನಾನು/ ರೋಗಿಗಳಾದ ನಾವು ಮತ್ತು ರೋಗಿಯ ಜೊತೆಯಲ್ಲಿರುವವರು ಕಾರ್ಯವಿಧಾನಗಳಲ್ಲಿ ಮತ್ತು ಮುಂದಿನ ಪರಿಣಾಮಗಳಿಗೆ ಸಂಪೂರ್ಣ ಜವಾಬ್ದಾರಿಯನ್ನು ಹೊಂದಿರುತ್ತೇವೆ. ಯಾವುದೇ ಅಹಿತಕರ ಪರಿಣಾಮಗಳಿಗಾಗಿ ನಾನು ಯಾವುದೇ ಚಿಕಿತ್ಸಾ ವೈದ್ಯರನ್ನು, ನರ್ಸಿಂಗ್ ಸಿಬ್ಬಂದಿಯನ್ನು ಮತ್ತು ಆಸ್ಪತ್ರೆಯ ಆಡಳಿತವನ್ನು ಹಿಡಿದಿಟ್ಟುಕೊಳ್ಳುವುದಿಲ್ಲ.

ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸಲು/ ಸೇರಲು, ನಾನು ನನ್ನ ಉತ್ತಮ ಮನಸ್ಸಿನಲ್ಲಿ ಸಂಪೂರ್ಣ ಒಪ್ಪಿಗೆಯನ್ನು ನೀಡಿರುತ್ತೇನೆ.

ರೋಗಿಯ ಸಹಿ

ಹೆಸರು:

ಸಾಕ್ಷಿಯ ಸಹಿ

ಹೆಸರು

ರೋಗಿಗೆ ಸಂಬಂಧ:

ಸ್ಥಳ;

SRI DEVARAJ URS ACADEMY OF HIGHER EDUCATION AND RESEARCH, **TAMAKA, KOLAR - 563101**

P	ROFORMA
CASE NO:	
UHID:	
SINGLE INTRA-ARTICULAR INJE PLASMA VERSUS CORTICOSTI	TITLE: IVE STUDY OF FLUOROSCOPIC GUIDED CCTION OF AUTOLOGOUS PLATELET RICHEROID IN DEGENERATIVE FACET JOINT NDOMISED CONTROL TRIAL"
1. BASIC DATA	
Name	Age/Sex
Address	
Mobile No.	
Date of Procedure	
Date of Admission/OP	
Date of Discharge	
History:	
General physical examination:	
Vitals: Pulse-	B.P-
RR-	Temp-

Systemic examin	ation:			
CVS-				
RS-				
PS-				
CNS-				
Preexisting syste	mic illness:			
Diabetes/Thyroid	disorder/ CVS/RS/ CNS/Locomotor/ TB/ Anemia/ Hypertension/			
Malnutrition/Othe	ers/Nil			
Local examination	on:			
Deformity	: Present/Absent			
Swelling	: Present/Absent			
Tenderness	: Present/Absent			
	R L			
Paraspinal muscle	spasm:			
SLRT	:			
Power	:			
L2 (Hip flexion)				
L3 (Knee	L3 (Knee extension)			
L4 (Ankle dorsiflexion)				
L5 (Great toe extension)				
S1 (Ankle plantar flexion)				
Distal sensation	:			
Distal pulsation :				

2. DIAGNOSIS:

3. INVESTIGATIONS:

• BLOOD: CBC

HIV, HCV, HBsAg status

RADIOLOGICAL: X ray LS spine - AP and LAT view
 MRI LS spine

4. TREATMENT:

- Intervention:
- Date:
- Type of anesthesia:

5. POST PROCEDURE:

- NSAID's :
- Other Medications:
- Physiotherapy :

Complications:

- Early:
- Delayed:
- Late:

Local complications

- 1. Necrosis of skin
- 2. Infection: a) Suspected/established
 - b) Superficial/deep
 - c) Mild/moderate/severe

- 3. Hematoma
- 4. Others

6. TIME OF DISCHARGE:

R L

Paraspinal muscle spasm:

SLRT :

Power :

L2 (Hip flexion)

L3 (Knee extension)

L4 (Ankle dorsiflexion)

L5 (Great toe extension)

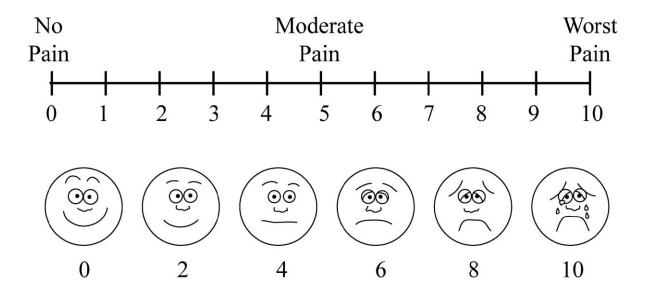
S1 (Ankle plantar flexion)

Distal sensation :

Distal pulsation :

SCORING SYSTEMS	BASELINE	4 WEEKS	8 WEEKS	12 WEEKS	6 MONTHS	1 YEAR
VAS						
PPI						
MODI						
RMQ						
SF-12						

VISUAL ANALOGUE SCALE (VAS SCORE)



PRESENT PAIN INTENSITY SCALE

(PPI)

	PPI		
Variable	Details		
0	NO PAIN		
1	MILD		
2	DISCOMFORTING	**************************************	
3	DISTRESSING		
4	HORRIBLE	<u> </u>	
5	EXCRUCIATION		

Pain Disability Questionnairea
ow your back pain has affected your ability to manage in everyday life. Pleas ibes your condition today. We realize you may feel that two of the statement SELY describes your current condition.
Standing I can stand as long as I want without increased pain. I can stand as long as I want, but it increases my pain. Pain prevents me from standing for more than 1 hour. Pain prevents me from standing for more than 1/2 hour. Pain prevents me from standing for more than 10 minutes. Pain prevents me from standing at all.
Sleeping Pain does not prevent me from sleeping well. I can sleep well only by using pain medication. Even when I take medication, I sleep less than 6 hours. Even when I take medication, I sleep less than 4 hours. Even when I take medication, I sleep less than 2 hours. Pain prevents me from sleeping at all.
Social Life My social life is normal and does not increase my pain. My social life is normal, but it increases my level of pain. Pain prevents me from participating in more energetic activities (e.g. sports, dancing). Pain prevents me from going out very often. Pain has restricted my social life to my home. I have hardly any social life because of my pain.
Traveling I can travel anywhere without increased pain. I can travel anywhere, but it increases my pain. My pain restricts my travel over 2 hours. My pain restricts my travel over 1 hour. My pain restricts my travel to short necessary journeys under 1/2 hour. My pain prevents all travel except for visits to the physician / therapist or hospital.
Employment / Homemaking My normal homemaking / job activities do not cause pain. My normal homemaking / job activities increase my pain, but I can still perform all that is required of me. I can perform most of my homemaking / job duties, but pain preven me from performing more physically stressful activities (e.g., lifting, vacuuming). Pain prevents me from doing anything but light duties. Pain prevents me from doing even light duties. Pain prevents me from performing any job or homemaking chores.

Roland-Morris Low Back Pain and Disability Questionnaire (RMQ)

Clinical improvement over time can be graded based on the analysis of serial questionnaire scores. If, for example, at the beginning of treatment, a patient's score was 12 and, at the conclusion of treatment, their score was 2 (10 points of improvement), would calculate as 83% (10/12 x 100) improvement

Patient name: UHID:

Date:

Please read instructions: When your back hurts, you may find it difficult to do some of the things you normally do. Mark only the sentences that describe you today.

- o I stay at home most of the time because of my back.
- o I change position frequently to try to get my back comfortable.
- o I walk more slowly than usual because of my back.
- o Because of my back, I am not doing any jobs that I usually do around the house.
- Because of my back, I use a handrail to get upstairs.
- o Because of my back, I lie down to rest more often.
- O Because of my back, I have to hold on to something to get out of an easy chair.
- O Because of my back, I try to get other people to do things for me.
- o I get dressed more slowly than usual because of my back.
- o I only stand up for short periods of time because of my back.
- o Because of my back, I try not to bend or kneel down.
- o I find it difficult to get out of a chair because of my back.
- o My back is painful almost all of the time.
- o I find it difficult to turn over in bed because of my back.
- My appetite is not very good because of my back.
- o I have trouble putting on my socks (or stockings) because of the pain in my back.
- o I can only walk short distances because of my back pain.
- o I sleep less well because of my back.
- o Because of my back pain, I get dressed with the help of someone else.
- o I sit down for most of the day because of my back.
- o I avoid heavy jobs around the house because of my back.
- o Because of back pain, I am more irritable and bad tempered with people than usual.
- o Because of my back, I go upstairs more slowly than usual.
- o I stay in bed most of the time because of my back.

SHORT FORM -12 HEALTH SCORE

(SF-12)

Scales	Items		Response categories	
	No.	Contents (abridged)		
PCS-12	1	General health	Excellent/Very good/Good/Fair/Poor	
	2	Moderate activities	Limited a lot/Limited a little/Not limited at all	
	3	Climb several flights of stairs	Limited a lot/Limited a little/Not limited at all	
	4	Accomplished less (physical)	Yes/No	
	5	Limited in kind of work	Yes/No	
	8	Pain - interference	Not at all/A little bit/Moderately/Quite a bit/Extremely	
MCS-12	6	Accomplished less (emotional)	Yes/No	
	7	Did work less careful	Yes/No	
	9	Calm and peaceful	All of the time/Most of the time/A good bit of the time/Some of the time/A little of the time/None of the time	
	10	Energy	All of the time/Most of the time/A good bit of the time/Some of the time/A little of the time/None of the time	
	11	Downhearted and blue	All of the time/Most of the time/A good bit of the time/Some of the time/A little of the time/None of the time	
	12	Social limitations - time	All of the time/Most of the time/Some of the time/A little of the time/None of the time	

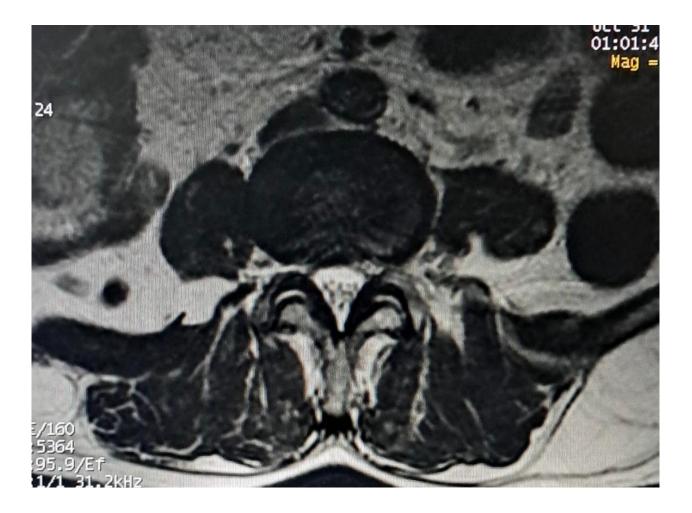


Figure 32: T2 Weighted MRI Axial Section showing bilateral FJ hypertrophy at L3-L4 level



Figure 33: T2 Weighted MRI Axial Section showing bilateral FJ hypertrophy at L4-L5 level

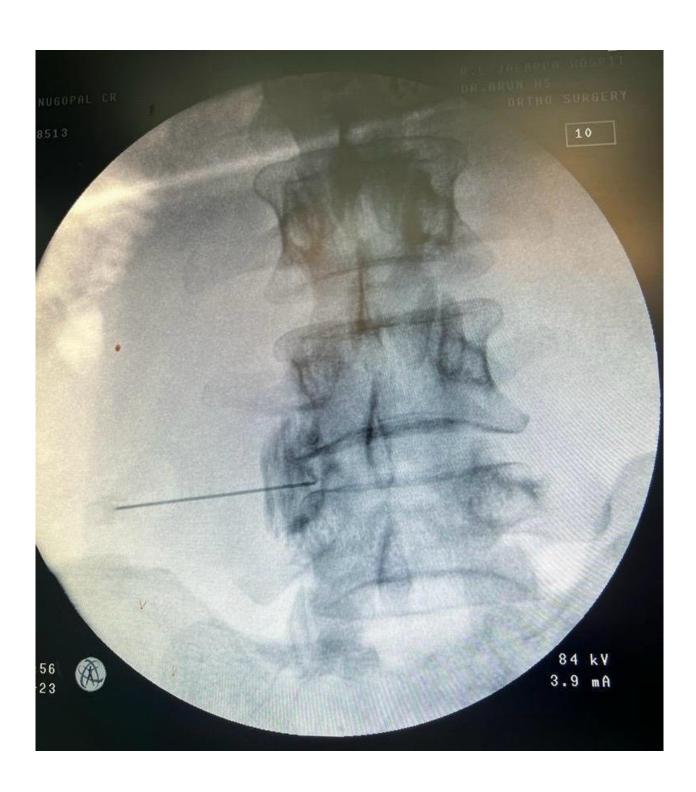


Figure 34: Spinal needle positioned at L4-L5 Right FJ



Figure 35: Spinal needle positioned at L4-L5 Left FJ



Figure 36: Sterile Kit for PRP injection



Figure 37 : Sterile Kit for Corticosteroid Injection



Figure 38: Dexamethasone Injection 4mg/ml



Figure 39: 22G spinal needle

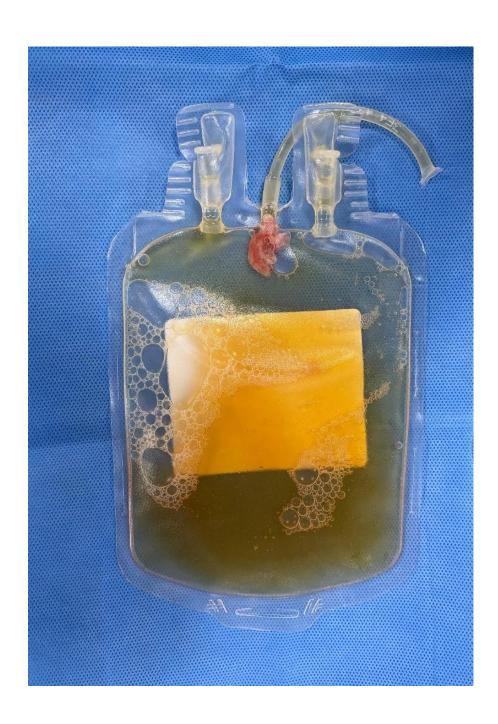


Figure 40: PRP separated in Blood Bag



Figure 41: PRP being withdrawn from the PRP bag

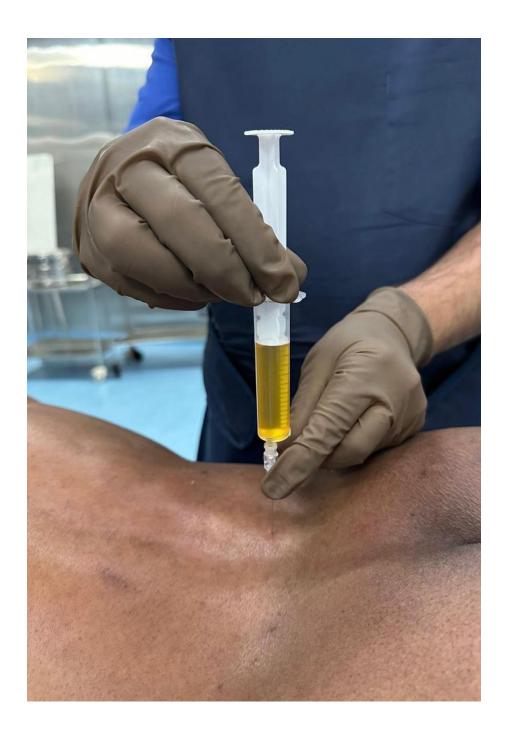


Figure 42: IA-PRP is injected into the targeted FJ



Figure 43: Positioning of patient and Injecting PRP into the targeted FJ

KEY TO MASTERCHART

BL	Base Line
F	Female
MODI	Modified Oswestry Low Back Pain Disability Index
M	Male
NBR	Number
PPI	Present Pain Index
RMQ	Roland-Morris Disability Questionnaire
SF 12	Short Form Health Score-12
UHID	Unique Hospital Identification
VAS	Visual Analogue Scale