WORLD INSTITUTE OF PAIN®

28th Annual Gabor Racz Advanced Interventional Pain Conference and Workshop

Budapest, Hungary August 25-27, 2025

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Sacroiliac Joint Procedures

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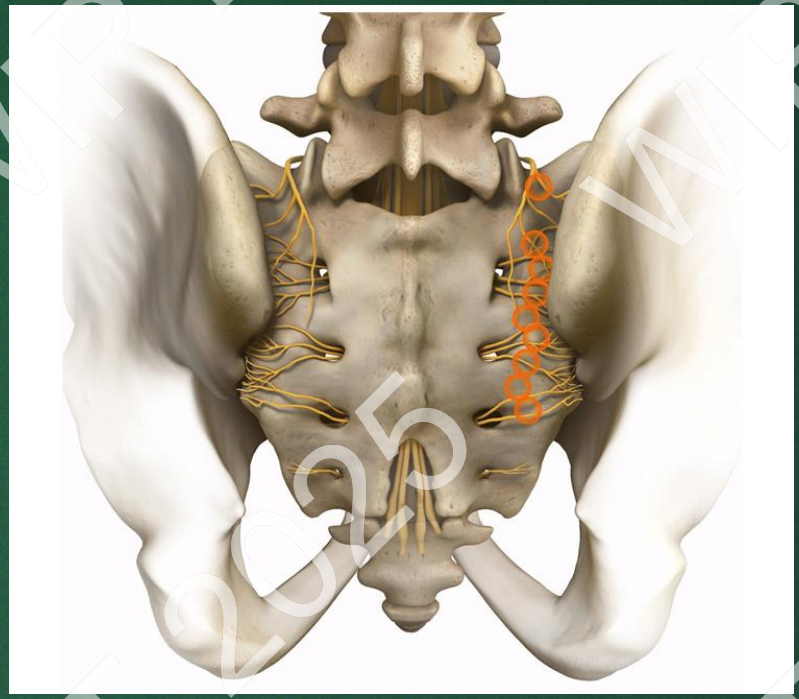


Disclosure:

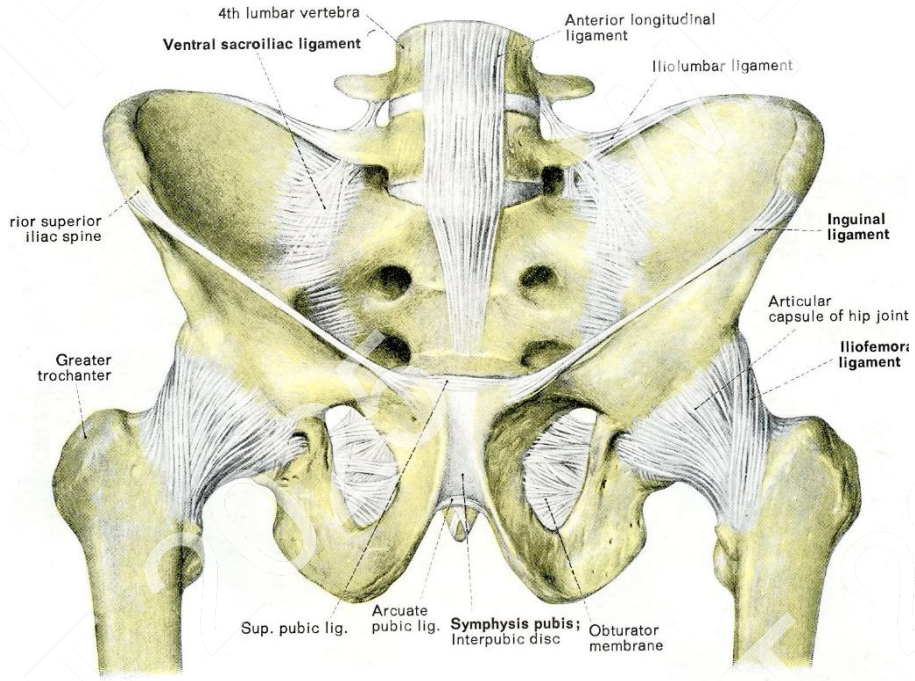
- Brand names mentioned only for identification purpose
- Consultant: Abbott, Avanos, Averitas Pharma, Biotronik, Boston Scientific, Medtronic, Nalu, NeuroOne, PainTeq, Saluda, SPR Therapeutics, Stryker
- Grant/Research Support: Avanos, Biotronik, Nalu, Nevro, NeuraLace, Saluda, SPR Therapeutics
- Stock Shareholder: NeuroOne

Learning Objectives:

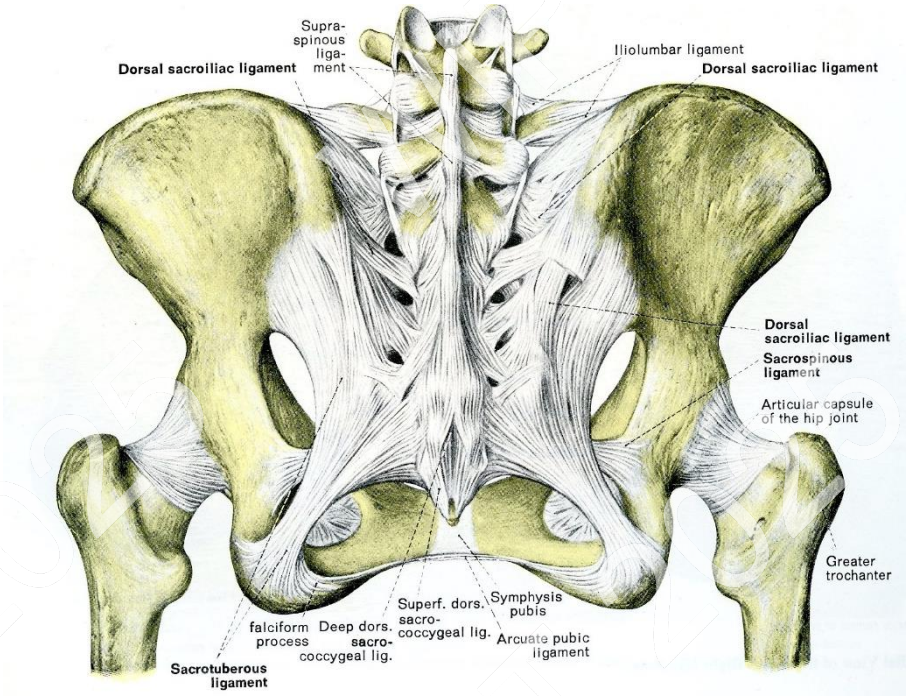
- Review sacroiliac joint anatomy
- Biomechanics of the SI joint
- Pathophysiology of sacroiliac joint dysfunction
- Clinical presentation of SI joint dysfunction
- Diagnostic work-up
- Current treatment options
- Emerging therapies and data

The Sacroiliac Joint

Ventral

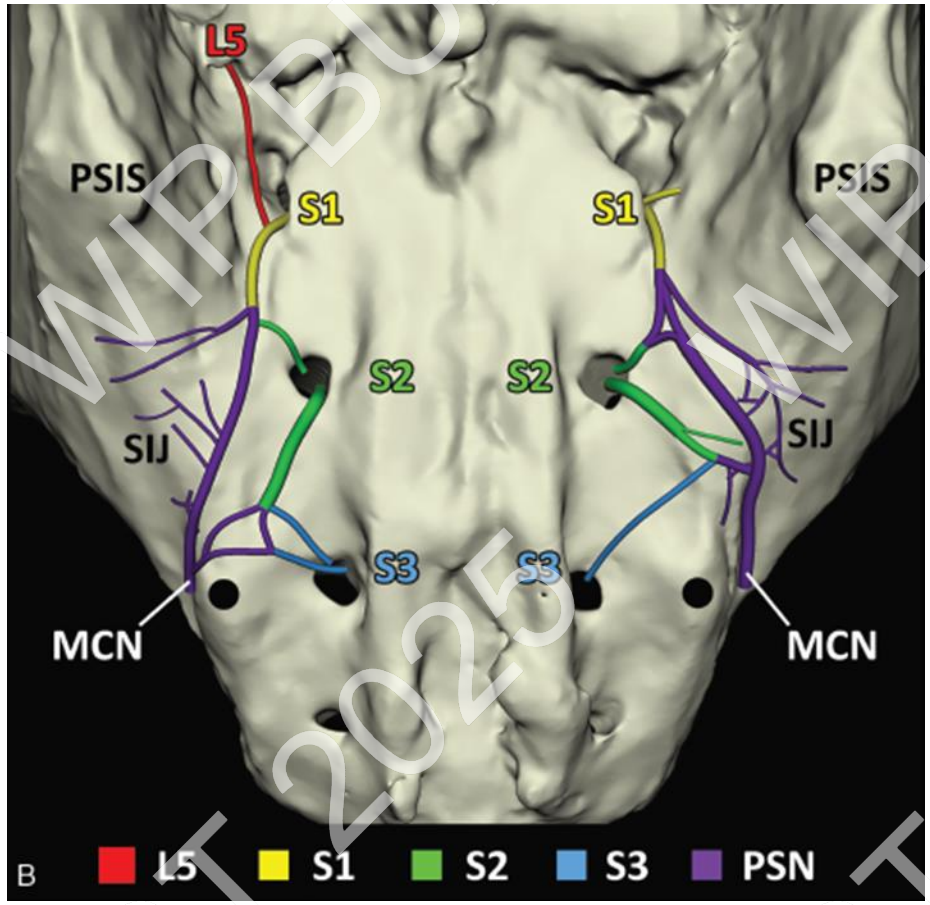


Dorsal



Source: Netter's Anatomy

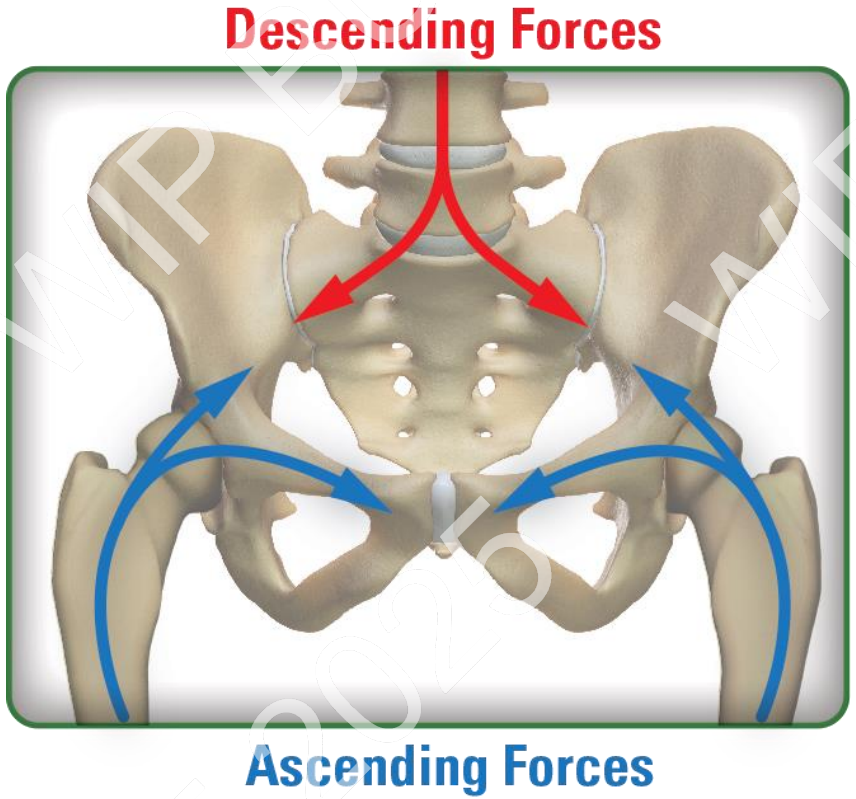
Sacroiliac Joint Anatomy



- Largest axial joint (17.5 cm^2)
- Diarthrodial joint
- Anterior: true synovial joint
- Posterior: syndesmosis
- Innervation:
  - (L4), L5 dorsal rami
  - S1-S3, (S4) lateral branches
  - (L4), L5, S1, S2 ventral rami

1. Cohen, S.,
2. Analg, 2005
3. Vanelderen, P. et al., Pain Practice, 2010

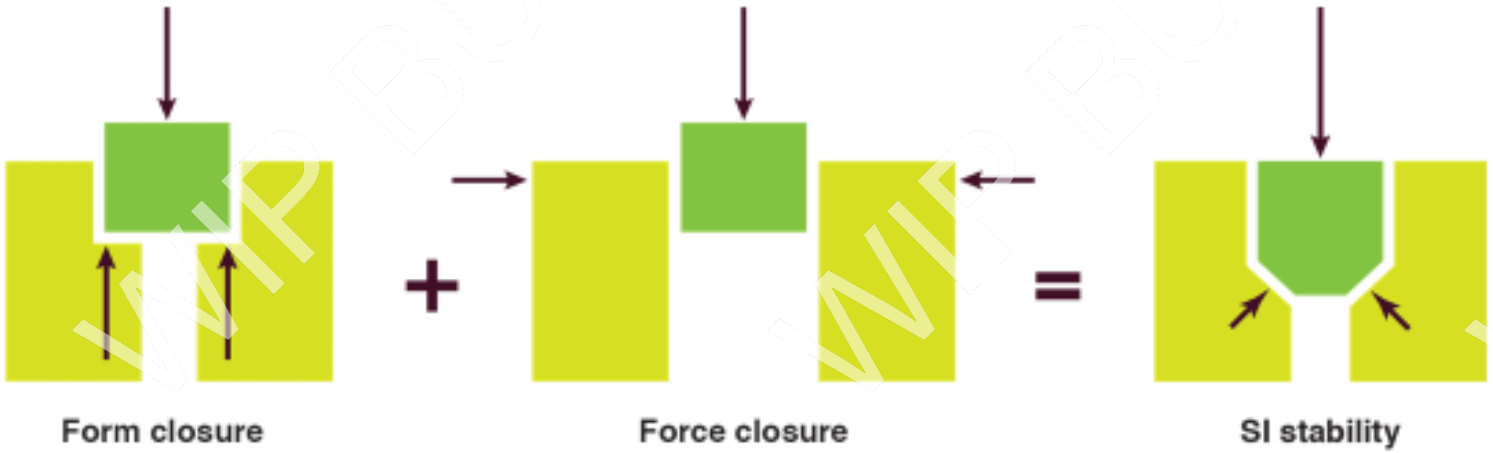
Sacroiliac Joint Biomechanics

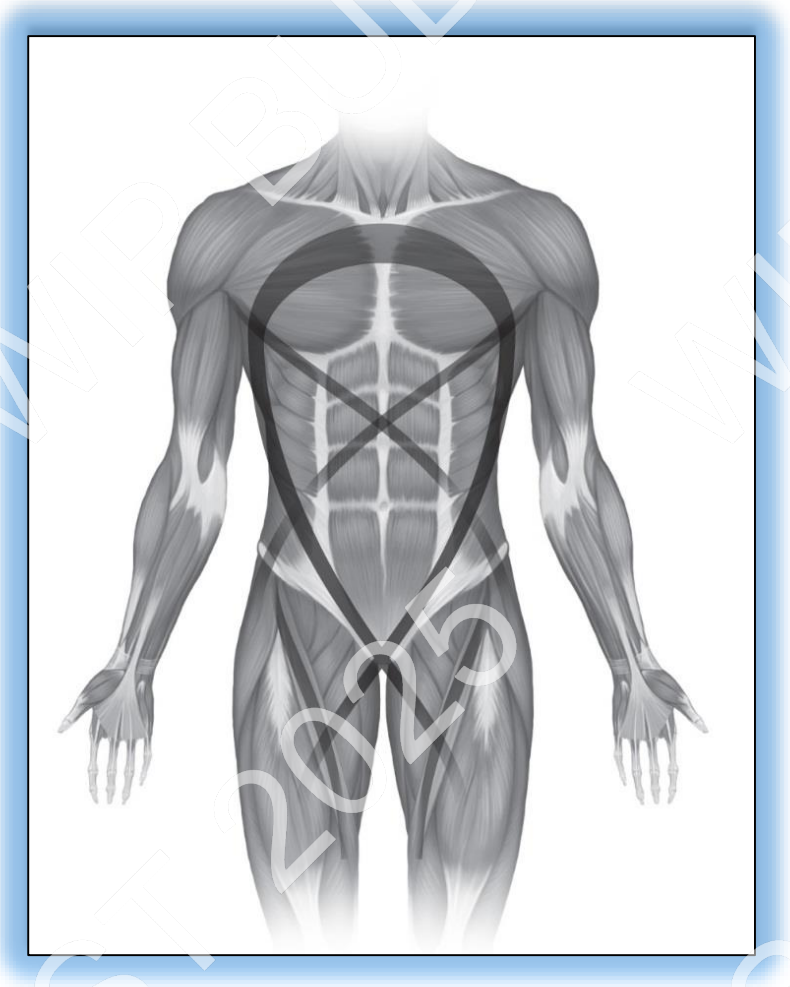


- Load bearing joint
- Stability > motion
- Motion in all 3 axes
- Transmission, dissipation
- Limiting X-axis rotation
- Facilitating parturition

1. Cohen, S., Anesth Analg, 2005
2. Sembrano, J., et al., Current Orthopaedic Practice, 2011

Biomechanics of the Sacroiliac Joint





Form Closure (Structural Integrity):
The shape and the integrity of the supporting ligaments

Force Closure (Joint Compression): External forces created stabilizing muscles, fascia, ligaments

Vleeming et al. The role of the pelvic girdle in coupling the spine and the legs: a clinical anatomical perspective on pelvic stability. In: Vleeming A., Mooney V., Stoeckart R., eds. Movement, stability and lumbopelvic pain. Second ed. Edinburgh: Elsevier; 2007:118

SI Joint Motion

Multi-planar motion

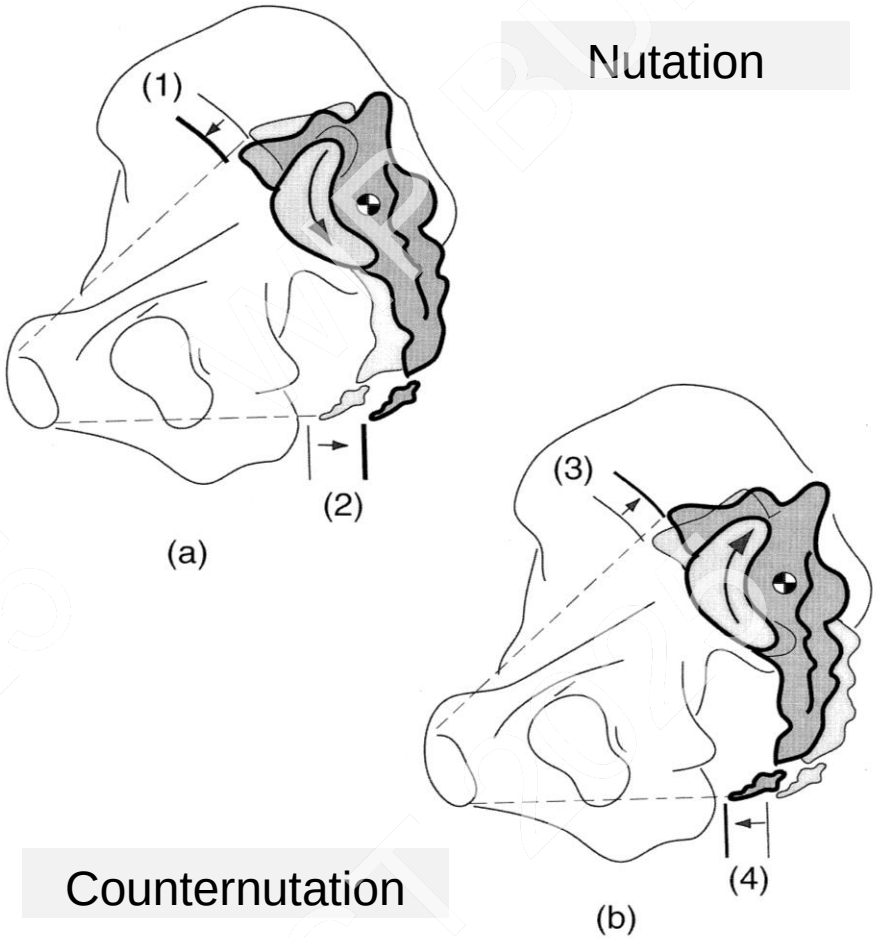
- Simultaneously rotate and translate through 3 axes of motion

Motions (<4° in any plane)

- **Nutation/Counternutation**
  - Primary motion
    - Males: 1 - 2°
    - Females: 2 - 4°

Sacral Translation

(A-P motion) up to 1.6mm



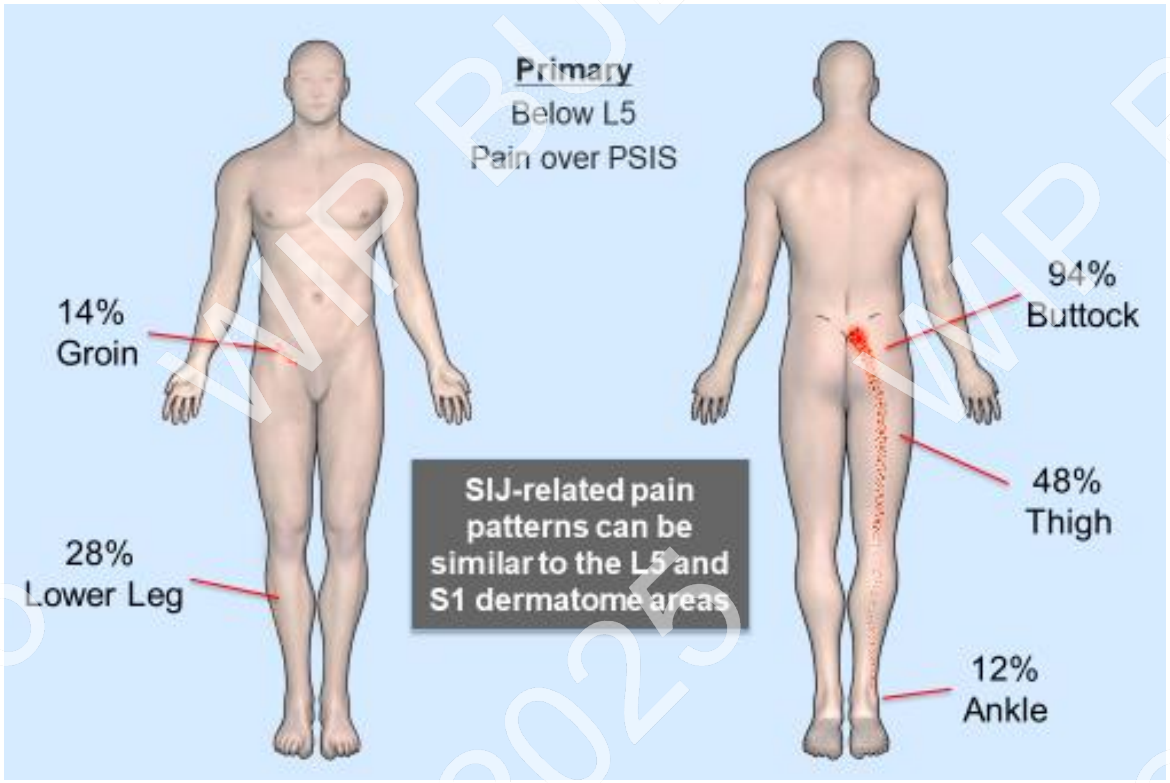
Sturesson et al. Spine 1989 Feb;14(2):162-5
Frost, et al. Pain Physician 2006

Epidemiology

- LBP most common reported pain complaint in adults, ~25%
- $200 billion/year, medical expenses, lost wages, and productivity
- SI joint pain 16-30% prevalence among LBP
- Post lumbar fusion: 61% prevalence of SI joint pain
- Computational model: L4-S1 fusion: max stress over SI joints
- N=130, lumbar fusion patients, 40% with LBP after lumbar fusion responded to 2 SI joint blocks

1. Sembrano, J. et al., Current Orthopaedic Practice, 2011
2. Cummings, J., and Capobianco, R., Annals of Surgical Innovation and Research, 2013
3. Ivanov, A. et al., Spine, 2009

Clinical Presentation and Pathophysiology



Intra-articular pain	Extra-articular pain
Arthritis	Ligamentous injury
Spondyloarthropathy	Bone fractures
Malignancies	Malignancies
Trauma	Myofascial pain
Infection	Enthesopathy
Cystic disease	Trauma Pregnancy

Vanelderen, P., et al., Pain Practice, 2010
Cohen SP et al. Expert Rev. Neurother. 13(1), 99–116 (2013)
Slipman, et al. Sacroiliac Joint Syndrome. Pain Physician 2001;4:2, pp 143-152
Fortin, J. et al. Spine 1994

Differential Diagnosis and Work-up

- Spondyloarthropathy
- Lumbar radiculopathy
- Facetogenic low back pain
- FBSS
- Hip pathology
- Pelvic pathology (endometriosis)
- Myofascial pain
- Piriformis syndrome

- Clinical history
- Surgical history
- Physical exam
- Imaging
- Diagnostic blocks

Provocative Tests

1. Distraction* (Highest PPV)
2. Thigh Thrust*
3. Compression*
4. FABER (Patrick's Test)
5. Gaenslen's Maneuver
6. Fortin Finger sign

Laslett et al. 3 of 6 tests:

Sensitivity: 94%

Specificity 78%

*most sensitive

PPV=positive predictive value

Laslett et al. Journal of Manual & Manipulative Therapy, 2008

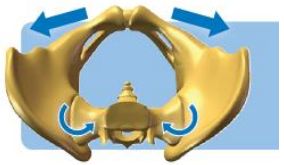
Distraction

Applies tensile forces on the anterior aspect of the SI joints

The patient lies supine and is asked to place their forearm behind their lumbar spine to support the natural lordosis.

A pillow is placed under the patient's knees. The examiner places their hands on the anterior and medial aspects of the patient's left and right ASIS with arms crossed and elbows straight.

A slow and steady pressure is applied by leaning toward the patient.

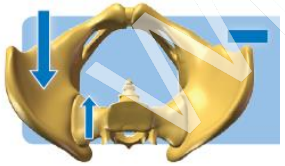


Thigh Thrust

Applies anteroposterior shear stress on the SI joint

The patient lies supine with one hip flexed to 90 degrees. The pelvis is stabilized at the opposite ASIS with the hand of the examiner.

The examiner stands on the same side as the flexed leg. The examiner provides steady increasing pressure through the axis of the femur.

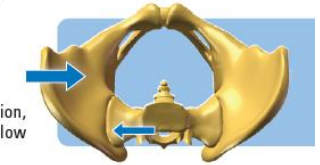


Compression

Applies lateral compression force across the SI joints

The patient is placed in a side-lying position, facing away from the examiner, with a pillow between the knees.

The examiner places a steady downward pressure through the anterior aspect of the lateral ilium, between the greater trochanter and iliac crest.



FABER

(Flexion, ABduction, External Rotation)

Applies tensile force on the anterior aspect of the SI joints

The patient lies supine as the examiner crosses the same-side foot over the opposite-side thigh. The pelvis is stabilized at the opposite ASIS with the hand of the examiner.

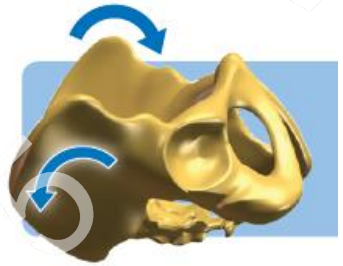
A gentle force is steadily increased on the same-side knee of the patient, exaggerating the motion of hip flexion, abduction, and external rotation.

Gaenslen

Applies torsional stress on the SI joints

The patient lies supine near the edge of the table and is asked to flex the opposite hip grasping their knee. This action "locks" the SI joint in position prior to the next step.

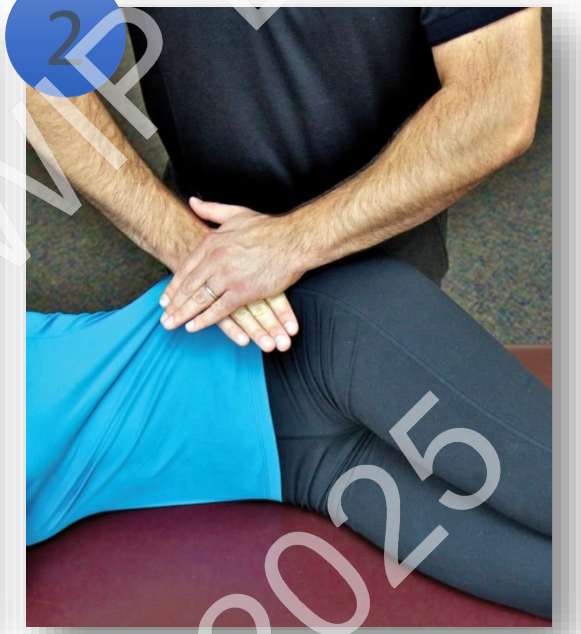
The examiner then slides the near-side leg (typically starting with the painful side) off the table and applies a steady extension force while simultaneously applying a flexion force through the opposite leg. The patient assists with the opposite-side hip flexion.



Courtesy of SI-Bone: www.SI-Bone.com

IASP: SI Joint Pain Diagnosis Criteria

Pain is present in the region of the SI joint



Provocative testing: reproduces patient's pain

SI Injecting relieves the patient of pain

Merskey 1994

IASP
International Association for the Study of Pain

Diagnostic Block

- SIJ block, assumed “gold standard”
- SIJ blocks have yet to be validated
- Lateral branch block?
- High false-positive rate, 17%
- “Double block”, not cost effective
- 22% accurate with blind injection
- Image guided is recommended

1. Cohen, S., Anesth Analg, 2005

2. Bogduk, N., Pain Medicine, 2009

3. Maigne, Y., et al, Spine, 1996

4. Rosenberg, J., Clin J Pain, 2000

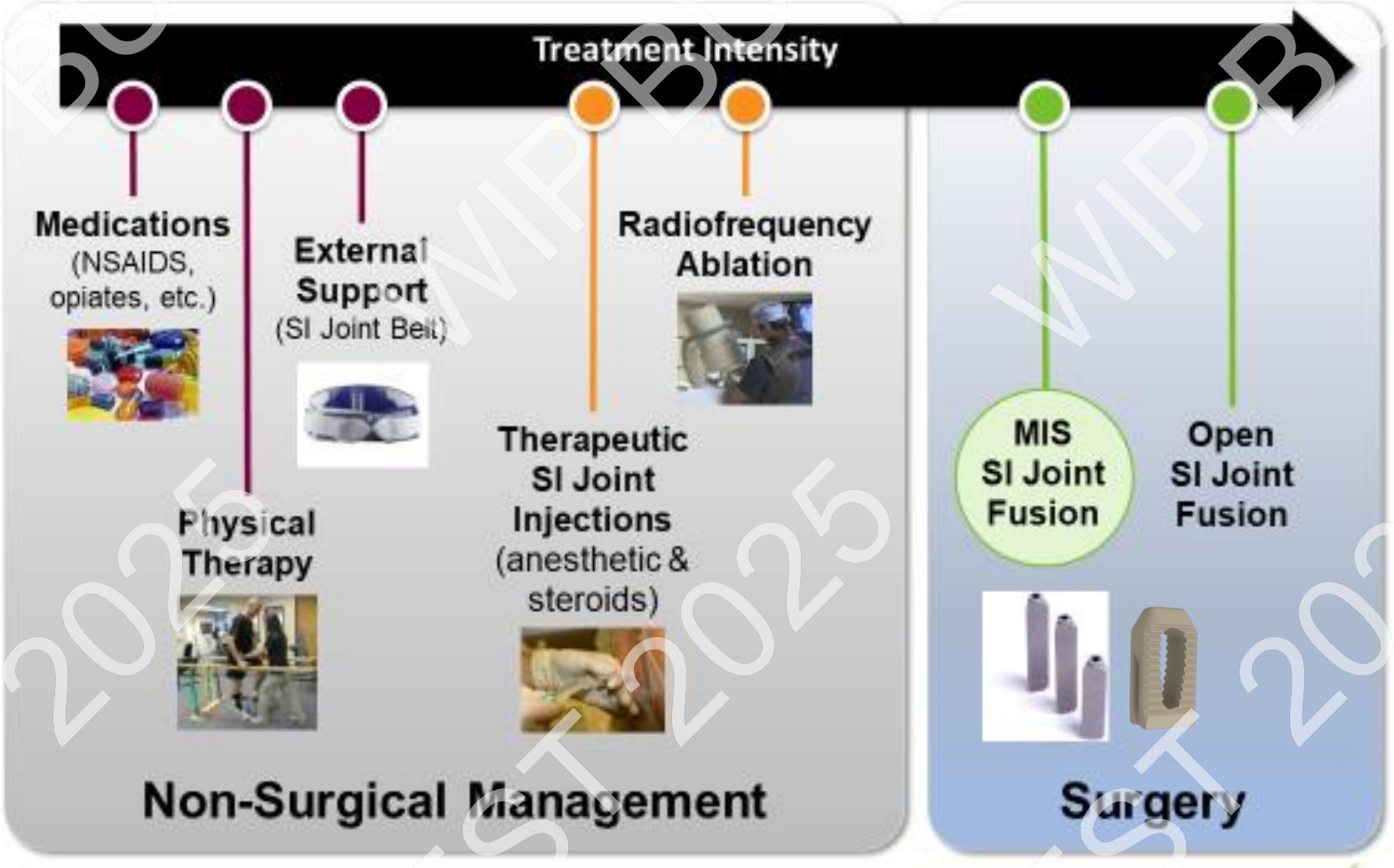
Pain Relieved with Anesthetic Injection

- **SI joint diagnostic injection is the referenced standard**
  - Fortin 2000, Szadek 2009, Laslett 2005
  - Guidelines from multiple pain societies
(IASP, AAMP&R, ASIPP-IPM, ASA, ASRA, SIS, WIP)
  - Guidelines from surgeon societies: ISASS, NASS

ISASS and ASIPP utilize ≥ 50% reduction in pain as a threshold

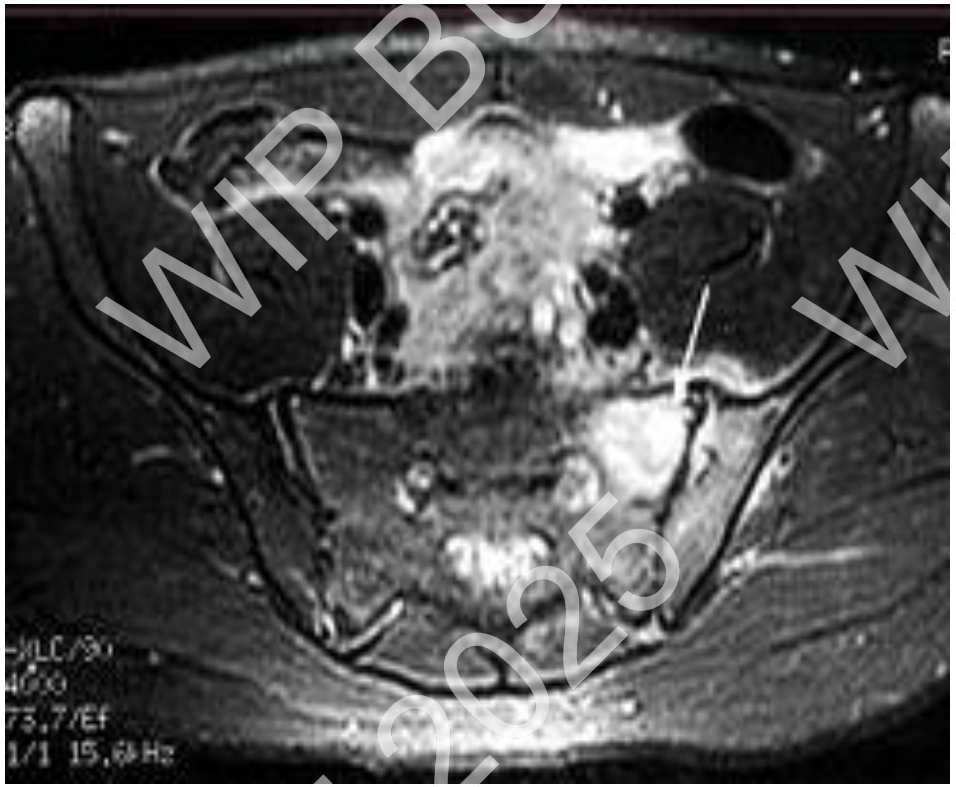
NASS utilizes ≥ 75% reduction in pain as a threshold

SI Joint Treatment Continuum



www.SI-Bone.com
www.PainTeq.com

Diagnostic Imaging



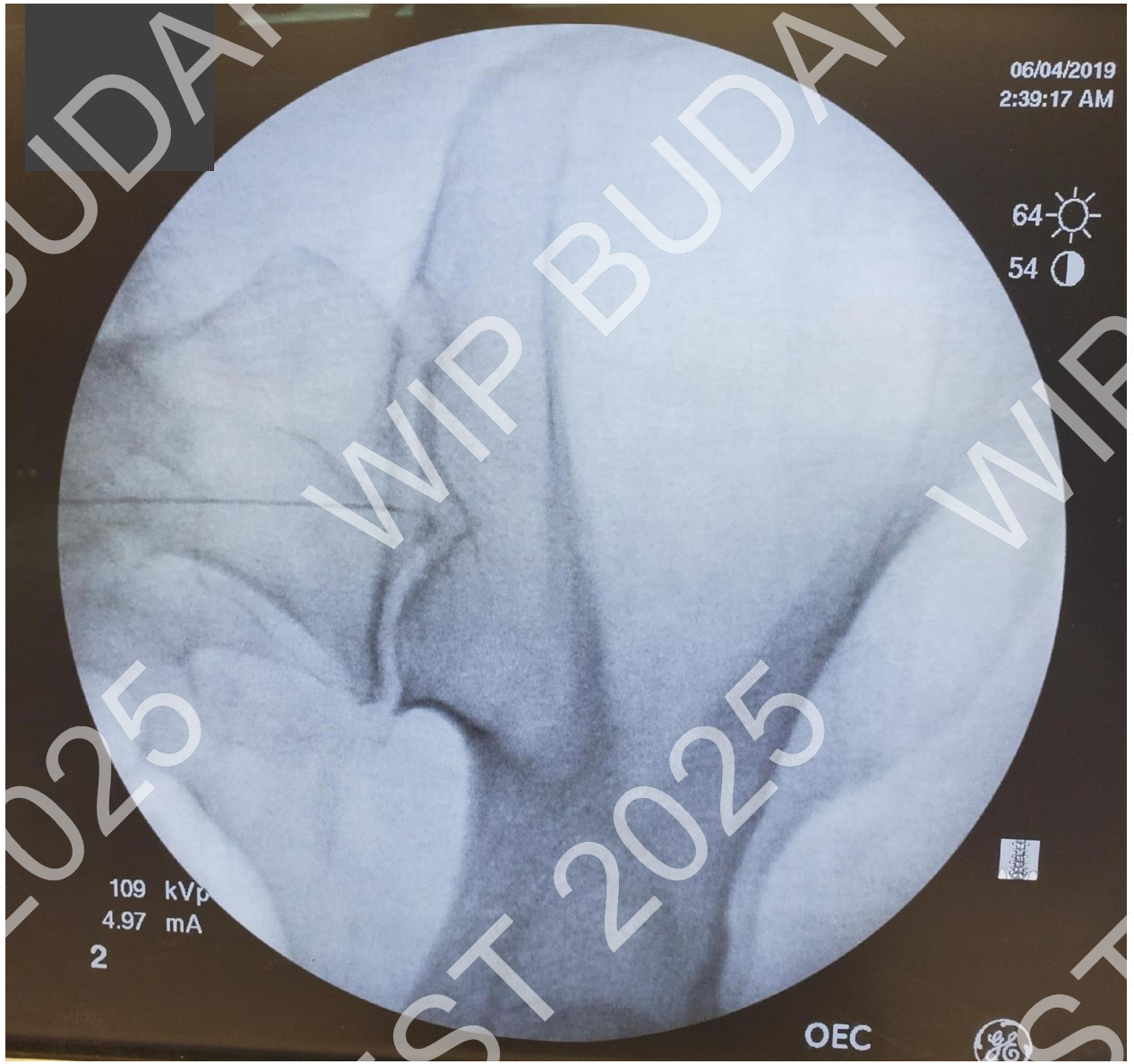
- Help rule out “red flags”
- No correlation between radiographic findings and SI joint pain
- MRI may show inflammation despite normal clinical exam

1.Vanelderen, P., et al., Pain Practice, 2010

2.Attarian, D., J South Orthp Assoc., 2001

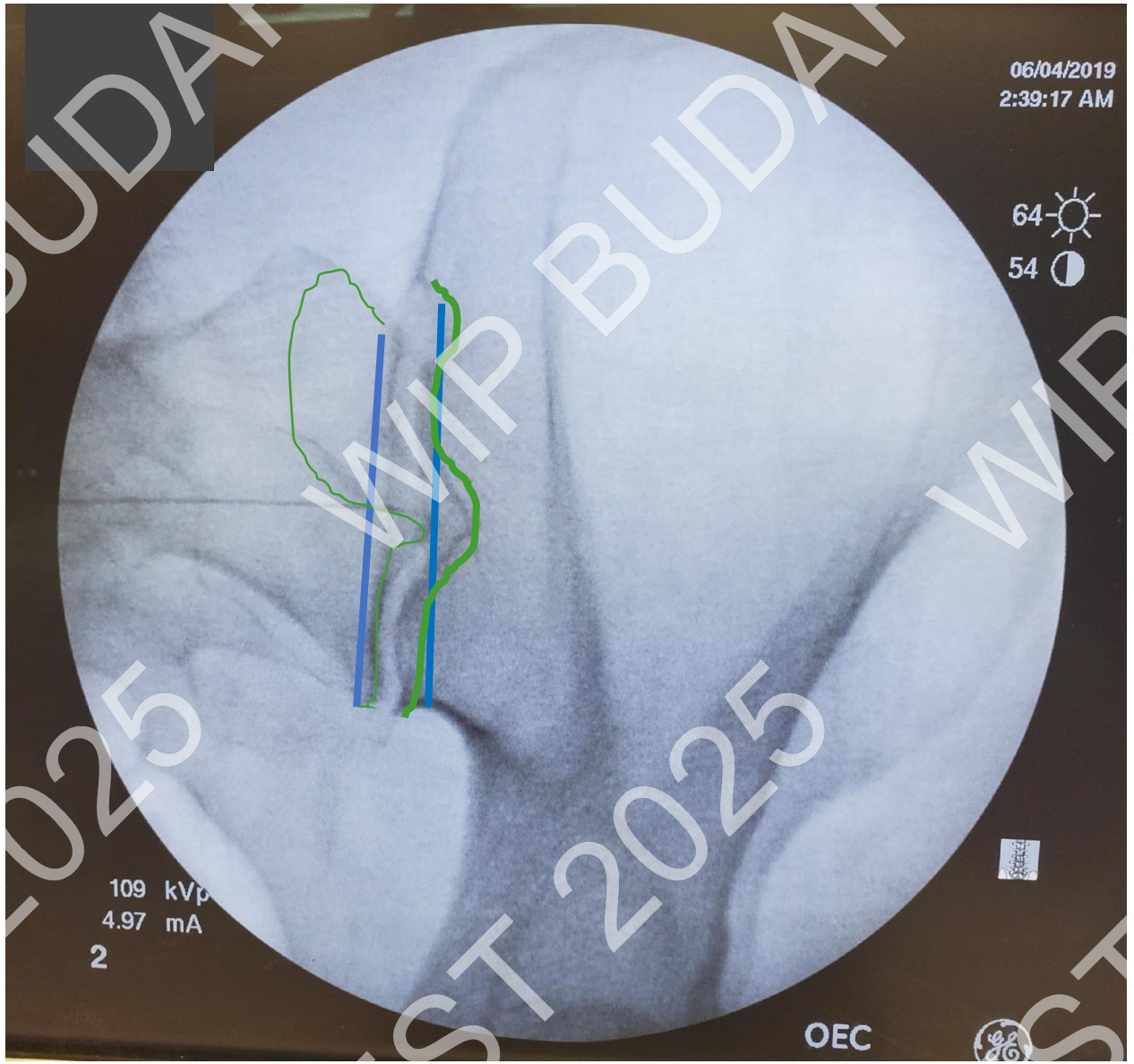
SIJ Anatomy:

- Medial Cortical Edge of the Anterior SIJ
- Lateral Cortical Edge of the Anterior SIJ
- Medial Cortical Edge of the Posterior SIJ
- Lateral Cortical Edge of the Posterior SIJ



SIJ Anatomy:

- Medial Cortical Edge of the Anterior SIJ
- Lateral Cortical Edge of the Anterior SIJ
- Medial Cortical Edge of the Posterior SIJ
- Lateral Cortical Edge of the Posterior SIJ



Hindawi
Pain Research and Management
Volume 2022, Article ID 3312589, 5 pages
https://doi.org/10.1155/2022/3312589

Review Article

Far-Contralateral Oblique (FCO) Sacroiliac Joint Injection: Description of a Novel Technique

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Sacroiliac (SI) joint arthropathy is the primary pain generator in approximately 15–25% of patients with axial low back pain and traditionally diagnosed with >50% pain reduction following an intra-articular injection localized to the inferior 1/3 of the SI joint. The conventional technique for accessing the SI joint encompasses a posterior approach with fluoroscopic guidance at 10–20° contralateral oblique angulation, and minor adjustments to this approach have been implemented with varying degrees of success. The authors present a novel technique for SI joint injection, infiltrating the middle third of the joint through an alternative far-contralateral oblique (FCO) approach, angulation between 20–40°. This approach theoretically endows easier access to the SI joint and at the very least provides another option for interventionalists in the diagnosis and treatment of sacroiliac joint pain. It can also be utilized to determine if a patient is a candidate for posterior percutaneous SI joint fusion. The authors sought to document this approach to ensure that it was both reproducible and safe, while recognizing the need for future studies.

1. Introduction

Axial low back pain (LBP) has been one of the primary causes of years lived with disability, and it continues to be an expanding burden on health systems as the global population continues to grow [1, 2]. Though some patients experience LBP originating from facet mediated and vertebrogenic pain, about 15–25% of patients with LBP have pain originating primarily from the sacroiliac joint (SIJ) [3]. As the treatments offered for SIJ mediated pain continue to evolve, appropriately diagnosing this diarthrodial joint as the primary pain mediator becomes even more critical. Obtaining a complete history, evaluating prior images, and performing a thorough physical examination evaluating the SIJ and surrounding structures are the initial steps to this process. If the SIJ is the presumed pathology, a diagnostic intra-articular SIJ injection with local anesthetic is performed and the diagnosis is further elucidated with greater than 50% pain relief, pinpointing the SIJ as the etiology for the LBP [4]. Traditionally, the intra-articular SIJ injections are targeted towards the inferior 1/3 of the SIJ. Due to patients' variable anatomy and pathological changes that occur with time, accessing the joint from this area may be challenging.

The use of a far-contralateral oblique approach has been recently adopted in use of posterior percutaneous allograft placement [5]. The use of sacroiliac joint intra-articular joint injections with the same approach requires further exploration and description. The procedure is detailed with the purpose of illustrating a novel but practical alternative approach for sacroiliac joint injections and to describe a reproducible method of performing the procedure.

Figure 1: Radiographic AP view of the pelvis illustrating location of PSIS. Note the PSIS position in relation to the needle entrance point (*) when utilizing FCO technique.

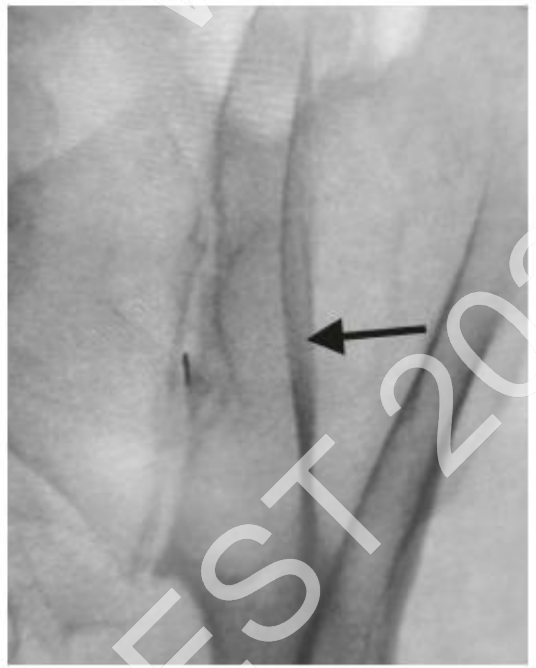
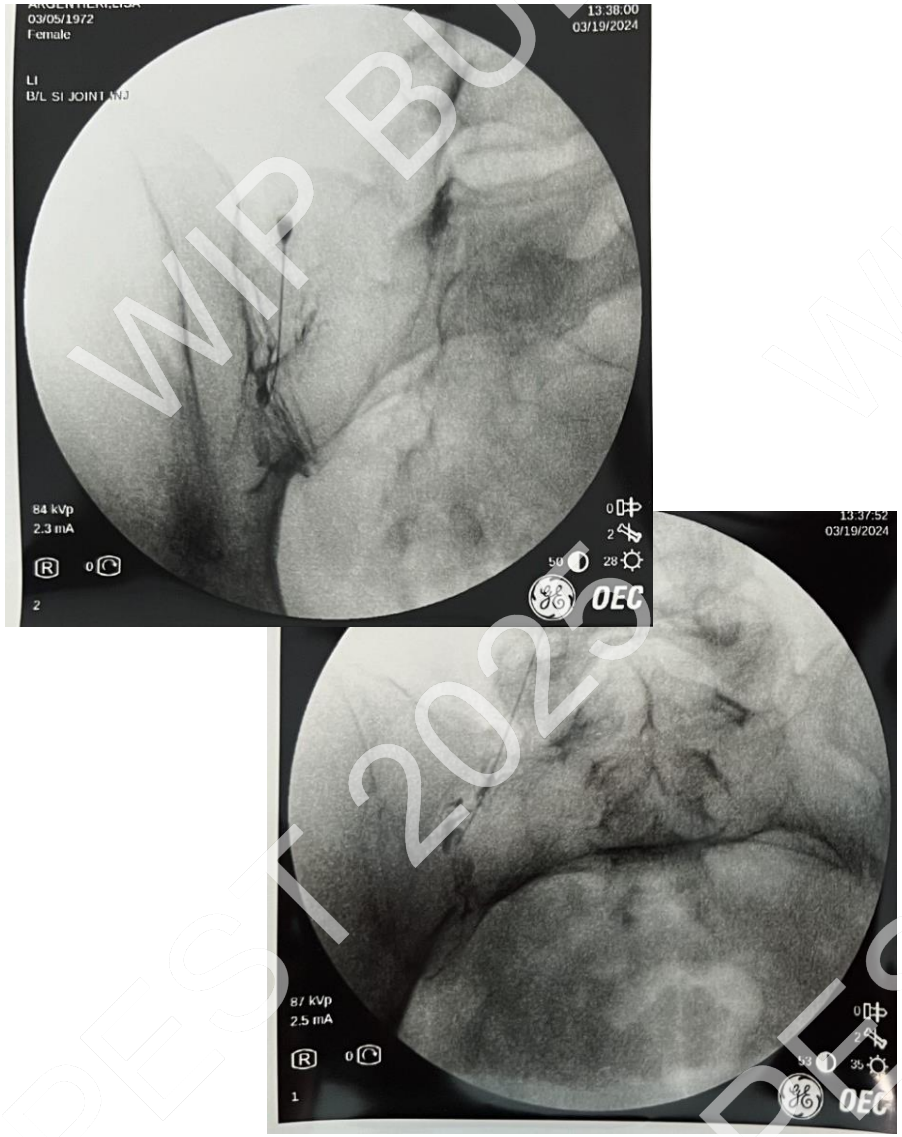


Figure 2: Contralateral oblique until PSIS is lateral to the SIJ line (black arrow).

Diagnostic SI Joint Injection



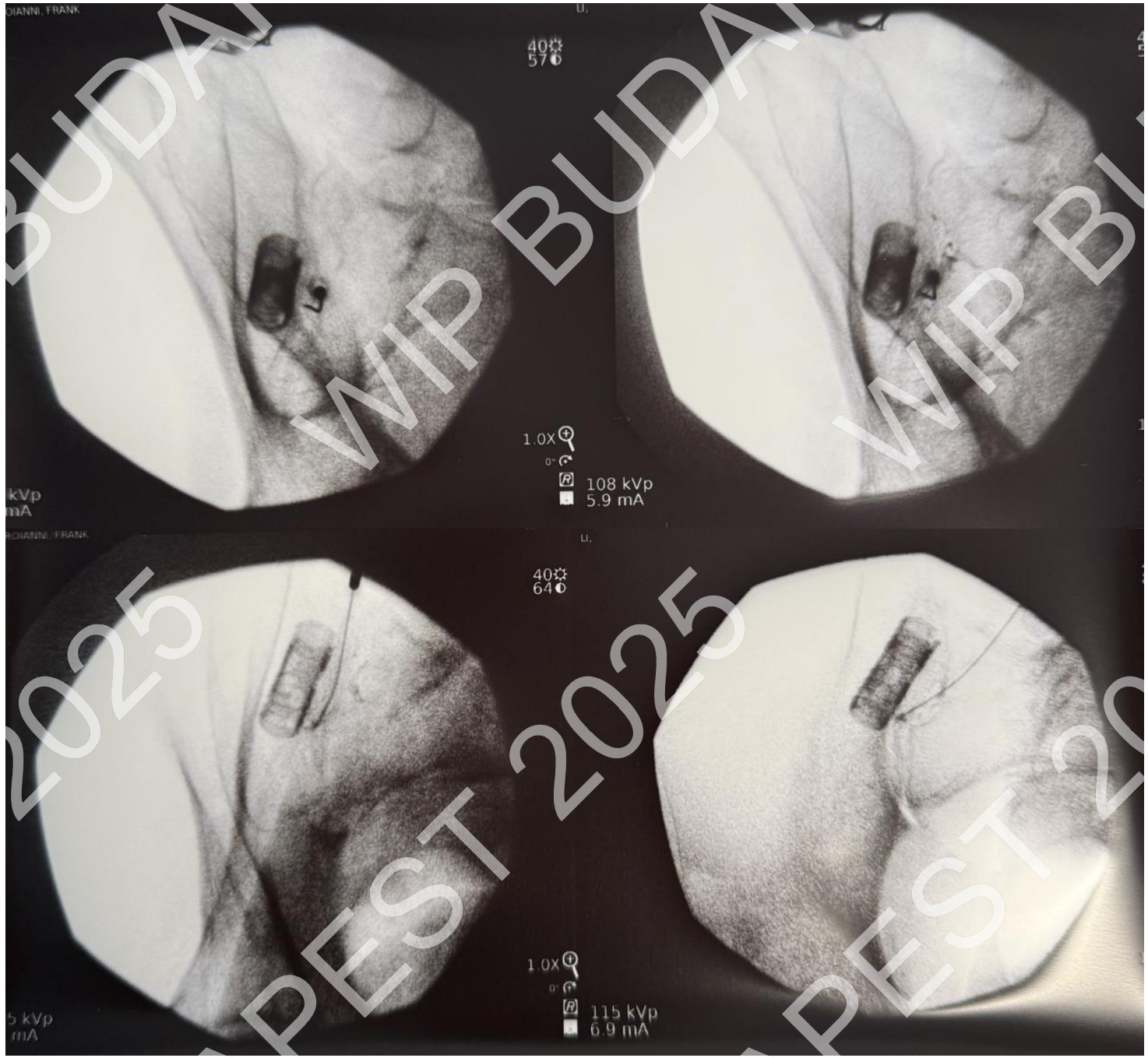
- SIJ injection, assumed “gold standard”
- Multiple views (AP, Lateral, Inlet)
- Lateral branch block
- High false-positive rate, 17%
- “Double block”, not cost effective
- Blind injection: 22% accuracy
- Image guidance is recommended

1. Cohen, S., Anesth Analg, 2005
2. Bogduk, N., Pain Medicine, 2009
3. Maigne, Y., et al, Spine, 1996
4. Rosenberg, J., Clin J Pain, 2000

Therapeutic Sacroiliac Joint Injection

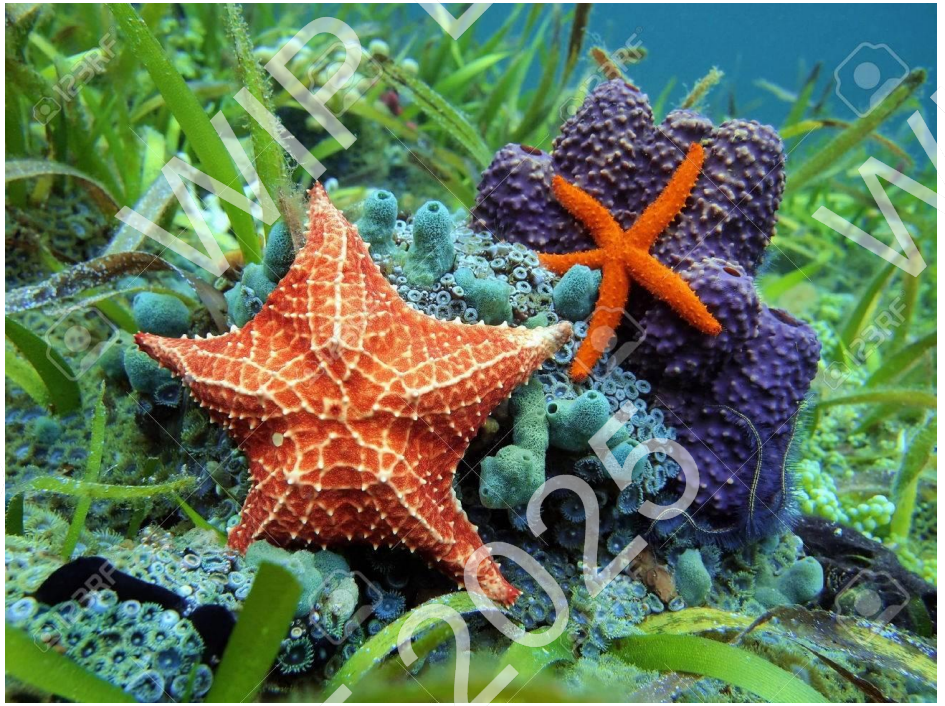
- Luukainen et al. established efficacy of EA SIJ injections
- Hawkins et al. N=155, 120 patients > 50% relief
- 45% had prior lumbar fusion
- Duration of follow up: 44 months
- 44 month follow up, average pain relief 9.3 months
- Mean 2.7 injections per patient
- Review by Cohen et al. showed EA as effective as IA
- Rosenberg et al. 22% accuracy of IA access without image guidance

Luukkainen, RK et al. Clin. Exp. Rheumatol. 20(1), 52–54 (2002)
Hawkins et al. Pain Med. 2009 Jul-Aug;10(5):850-3
Cohen SP et al. Expert Rev. Neurother. 13(1), 99–116 (2013)
Rosenberg JM et al. Clin. J. Pain 16(1), 18–21 (2000)


40
57
1.0X
108 kVp
5.9 mA
40
64
1.0X
115 kVp
6.9 mA

Regenerative Medicine

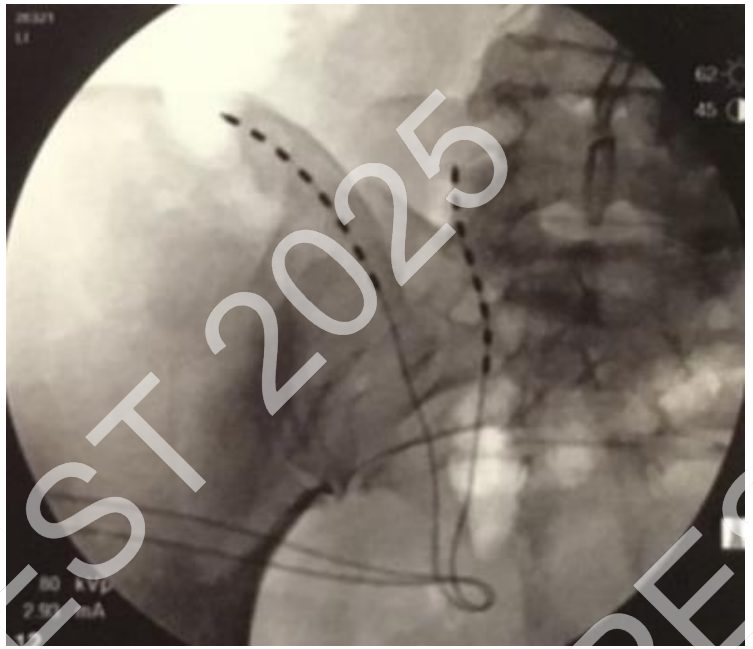
- Prolotherapy
- Dextrose vs triamcinolone: at 15 months
  - 58.7% vs 10.2% (Kim et al.)
- Platelet rich plasma (PRP)
- PRP vs methylprednisolone: at 3 months
  - 90% vs 25% (Singla et al.)
- Stem cell therapy?
- Current evidence is lacking



Kim WM et al. J Altern Complement Med 2010;16:1285-1290
Singla, V et al. Pain. Pain Pract 2017
Burnham, T. et al. Pain Medicine, 21(10), 2020, 2518–2528s

Peripheral Nerve Stimulation

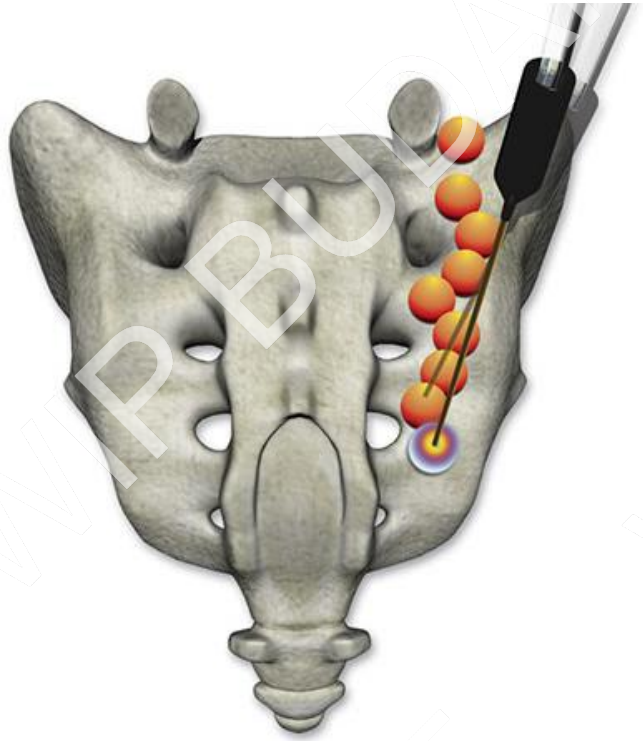
- Peripheral nerve stimulation is “hot”
- Lateral branch nerve stimulation is an alternative to ablation
- Goroszeniuk et al. retrospective cohort study: PNS for SIJ pain
- Utilizing a SCS device
- VAS 8.7→1.1
- Patient satisfaction 80-100%
- 75% reduction in analgesic (?) medications
- No reported complications

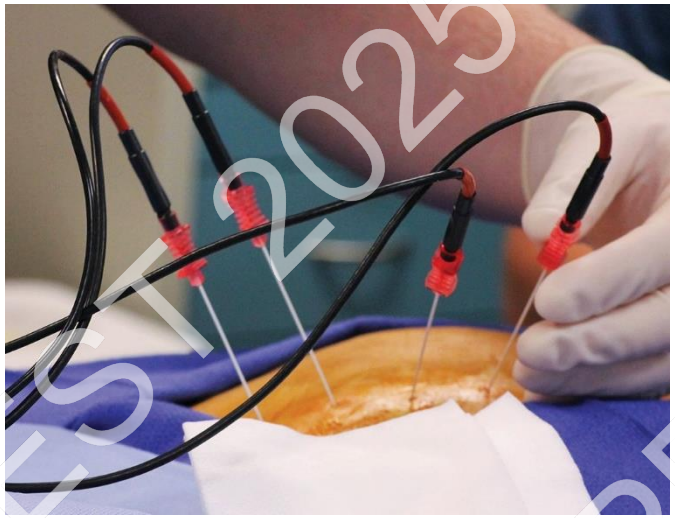


Goroszeniuk et al. Neuromodulation 2019; 22: 661–666

Radiofrequency Ablation

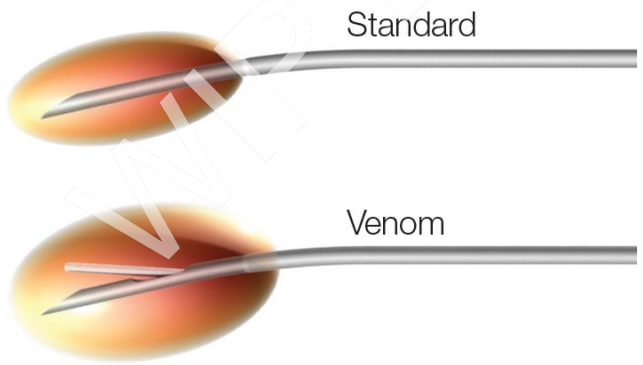
- Conventional radiofrequency (CRF): 55-90 ℃
- Pulsed radiofrequency (PRF): <42 ℃
- Water-cooled radiofrequency (WCRF): 55-60 ℃
- Intra-articular leapfrog technique
- Palisade pattern RF +/- bipolar
- Multi-contact bi-polar wands
- Retractable RF needles
- Multi-electrode probe

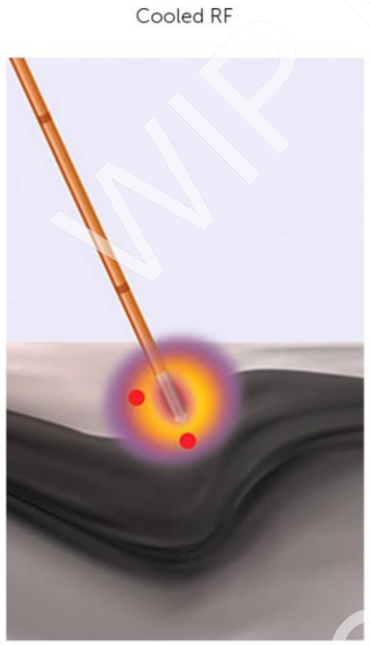


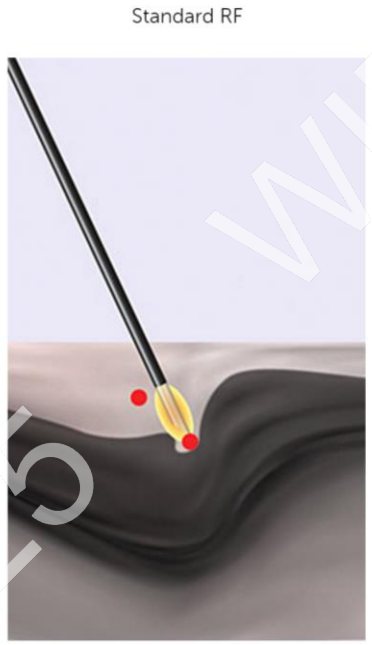


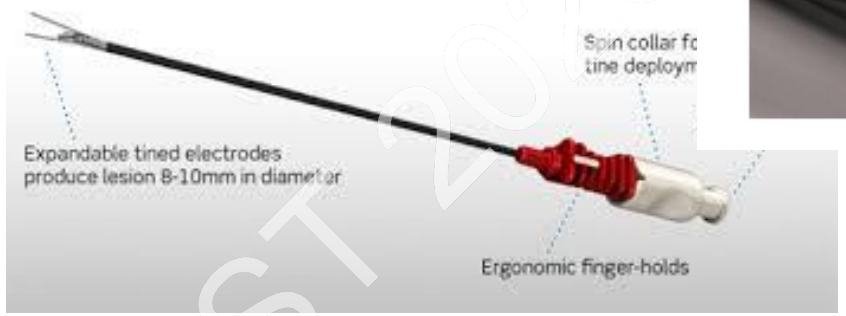
https://avanospainmanagement.com/solutions/chronic-pain/si-joint/

RF Options and Controversies









www.strykerivs.com
www.nimbusconcepts.com
www.avanos.com
www.abbott.com

Evidence: Radiofrequency Ablation for SIJ Pain

- Similar spinal RF was first described by Shealy in 1970's
- Conventional thermal RF effective up to 6 months, Aydin et al.
- Cohen et al. was the first to compare cooled RF to conventional RF
- Conflicting results from Cheng et al.
- Recent publication by Cohen et al. supports efficacy of cooled RF ablation

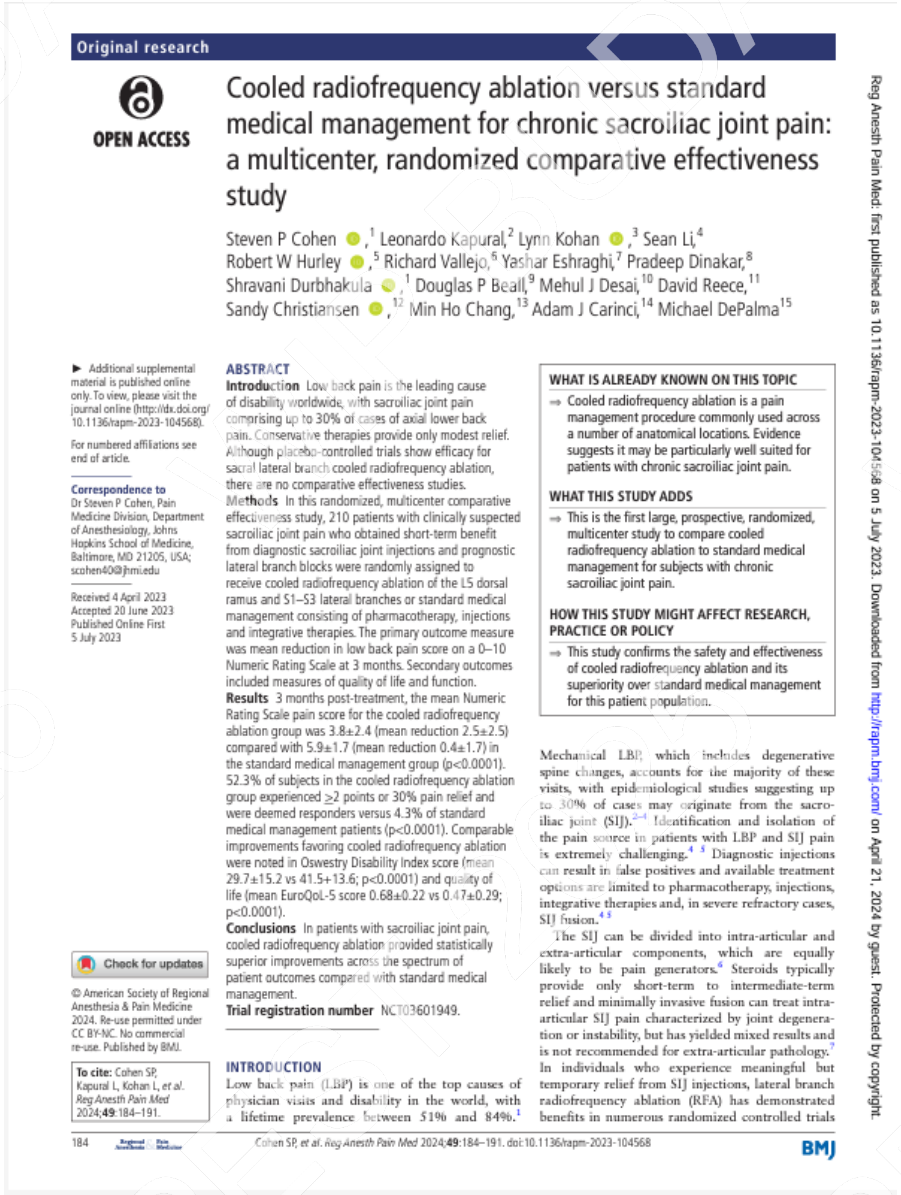
Shealy CN. J. Neurosurg. 43(4), 448–451 (1975)
Aydin SM. et al. PM R. 2(9), 842–851 (2010)
Cheng, J., et al. Clin J Pain, 2013

Randomized Placebo-Controlled Study Evaluating Lateral Branch Radiofrequency Denervation for Sacroiliac Joint Pain

Steven P. Cohen, M.D. [Associate Professor][*], Robert W. Hurley, M.D., Ph.D. [Assistant Professor][**], Chester C. Buckenmaier III, M.D. [Associate Professor][#], Connie Kurihara, R.N. [Research Assistant][##], Benny Morlando, R.N. [Research Assistant][##], and Anthony Dragovich, M.D. [Assistant Professor][*#]

- N=28, randomized sham-controlled study
- Utilizing Cooled RF
- 57% reported greater than 50% pain relief at 6 month
- 14% at 1 month for placebo group
- Crossover, n=11: 36% at 6 months

Cohen, S., et al. Anesthesiology, 2008



Original research

OPEN ACCESS

Cooled radiofrequency ablation versus standard medical management for chronic sacroiliac joint pain: a multicenter, randomized comparative effectiveness study

Steven P Cohen ,[1] Leonardo Kapural,[2] Lynn Kohan ,[3] Sean Li,[4] Robert W Hurley ,[5] Richard Vallejo,[6] Yashar Eshraghi,[7] Pradeep Dinakar,[8] Shravani Durbhakula ,[1] Douglas P Beall,[9] Mehul J Desai,[10] David Reece,[11] Sandy Christiansen ,[12] Min Ho Chang,[13] Adam J Carinci,[14] Michael DePalma[15]

► Additional supplemental material is published online only. To view, please visit the journal online (http://dx.doi.org/10.1136/rapm-2023-104568).

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ABSTRACT

Introduction Low back pain is the leading cause of disability worldwide, with sacroiliac joint pain comprising up to 30% of cases of axial lower back pain. Conservative therapies provide only modest relief. Although placebo-controlled trials show efficacy for sacral lateral branch cooled radiofrequency ablation, there are no comparative effectiveness studies.

Methods In this randomized, multicenter comparative effectiveness study, 210 patients with clinically suspected sacroiliac joint pain who obtained short-term benefit from diagnostic sacroiliac joint injections and prognostic lateral branch blocks were randomly assigned to receive cooled radiofrequency ablation of the L5 dorsal ramus and S1–S3 lateral branches or standard medical management consisting of pharmacotherapy, injections and integrative therapies. The primary outcome measure was mean reduction in low back pain score on a 0–10 Numeric Rating Scale at 3 months. Secondary outcomes included measures of quality of life and function.

Results 3 months post-treatment, the mean Numeric Rating Scale pain score for the cooled radiofrequency ablation group was 3.8±2.4 (mean reduction 2.5±2.5) compared with 5.9±1.7 (mean reduction 0.4±1.7) in the standard medical management group (p<0.0001). 52.3% of subjects in the cooled radiofrequency ablation group experienced ≥2 points or 30% pain relief and were deemed responders versus 4.3% of standard medical management patients (p<0.0001). Comparable improvements favoring cooled radiofrequency ablation were noted in Oswestry Disability Index score (mean 29.7±15.2 vs 41.5+13.6; p<0.0001) and quality of life (mean EuroQoL-5 score 0.68±0.22 vs 0.47±0.29; p<0.0001).

Conclusions In patients with sacroiliac joint pain, cooled radiofrequency ablation provided statistically superior improvements across the spectrum of patient outcomes compared with standard medical management.

Trial registration number NCT03601949.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Cooled radiofrequency ablation is a pain management procedure commonly used across a number of anatomical locations. Evidence suggests it may be particularly well suited for patients with chronic sacroiliac joint pain.

WHAT THIS STUDY ADDS

⇒ This is the first large, prospective, randomized, multicenter study to compare cooled radiofrequency ablation to standard medical management for subjects with chronic sacroiliac joint pain.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ This study confirms the safety and effectiveness of cooled radiofrequency ablation and its superiority over standard medical management for this patient population.

Check for updates

To cite: Cohen SP, Kapural L, Kohan L, *et al*. *Reg Anesth Pain Med* 2024;**49**:184–191.

INTRODUCTION

Low back pain (LBP) is one of the top causes of physician visits and disability in the world, with a lifetime prevalence between 51% and 84%.[1]

Mechanical LBP, which includes degenerative spine changes, accounts for the majority of these visits, with epidemiological studies suggesting up to 30% of cases may originate from the sacroiliac joint (SIJ).[2–4] Identification and isolation of the pain source in patients with LBP and SIJ pain is extremely challenging.[4 5] Diagnostic injections can result in false positives and available treatment options are limited to pharmacotherapy, injections, integrative therapies and, in severe refractory cases, SIJ fusion.[4 5]

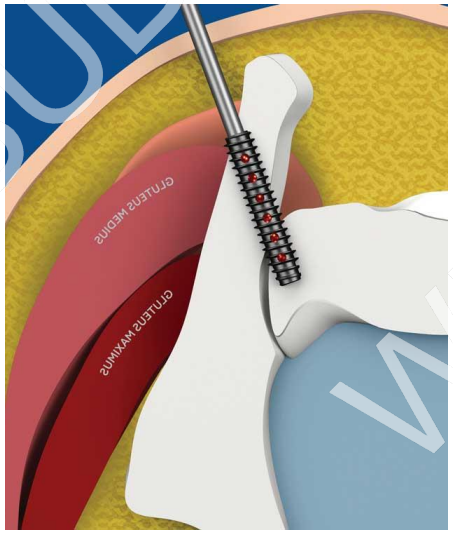
The SIJ can be divided into intra-articular and extra-articular components, which are equally likely to be pain generators.[6] Steroids typically provide only short-term to intermediate-term relief and minimally invasive fusion can treat intra-articular SIJ pain characterized by joint degeneration or instability, but has yielded mixed results and is not recommended for extra-articular pathology.[7] In individuals who experience meaningful but temporary relief from SIJ injections, lateral branch radiofrequency ablation (RFA) has demonstrated benefits in numerous randomized controlled trials

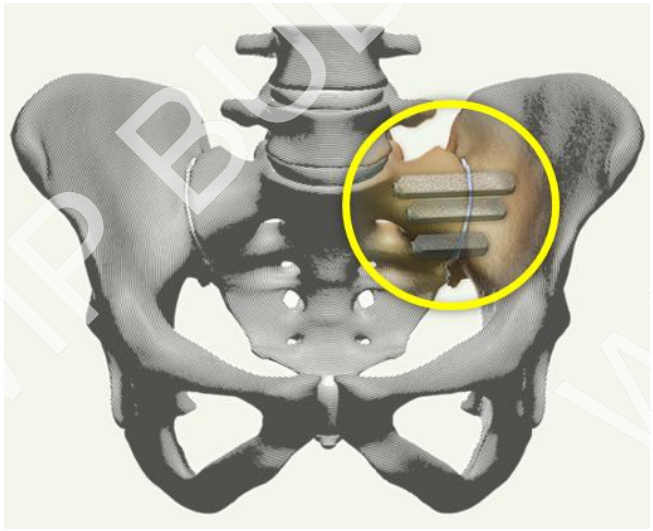
CRF versus Medical Management

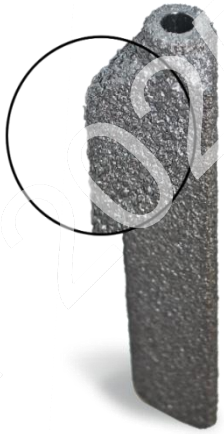
- Randomized, multicenter comparative study with crossover
- 210 patients, cooled RF after responding to LBB or CMM
- CMM group allowed to cross over at 3 months
- CRF group, 2.5 ± 2.5 mean reduction NRS (52.3% responders)
- CMM group, 0.4 ± 1.7 mean reduction NRS (4.3% responders)
- Improvements in ODI, EQ-5D

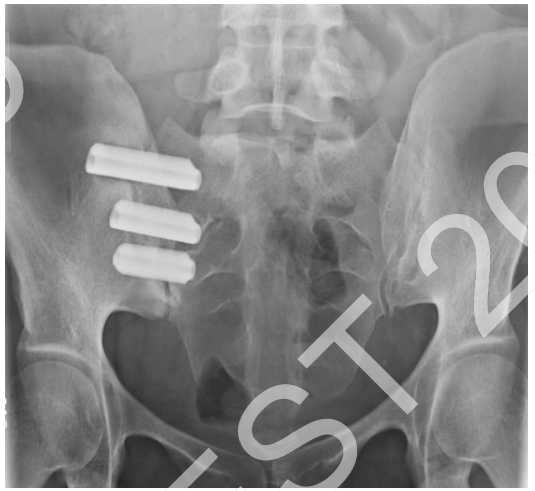
Sacroiliac Joint Fusion

- Open SI joint fusion (trauma)
- Minimally Invasive SI joint Fusion
- For chronic SI joint pain/dysfunction
- Lateral versus Posterior
- Metallic versus Bone allograft
- Screw versus triangular implant





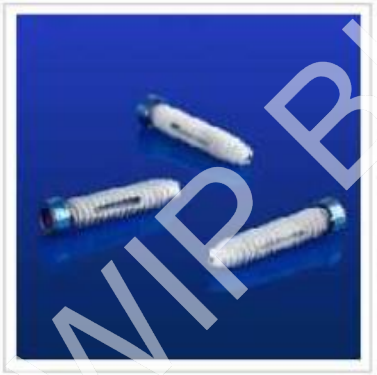




www.Medtronic.com
www.SI-bone.com
www.painteq.com

Percutaneous SI Joint Fusion



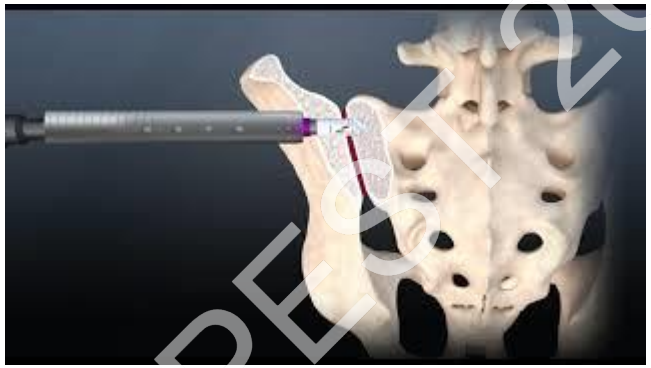
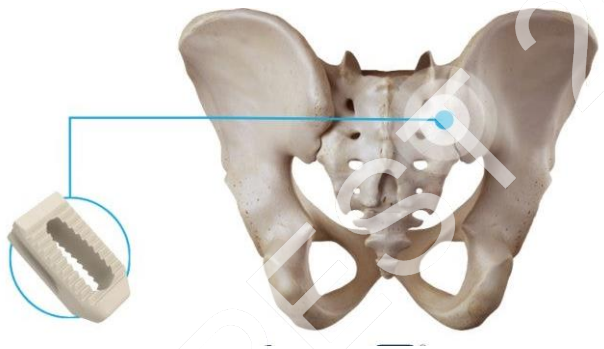
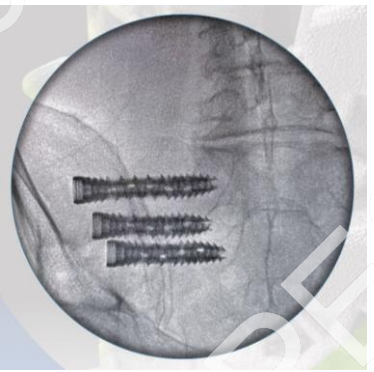










Two-Year Outcomes from a Randomized Controlled Trial of Minimally Invasive Sacroiliac Joint Fusion vs. Non-Surgical Management for Sacroiliac Joint Dysfunction

David W. Polly, MD,[1] John Swofford, MD,[2] Peter G. Whang, MD,[3] Clay J. Frank, MD,[4] John A. Glaser, MD,[5] Robert P. Limoni, MD,[6] Daniel J. Cher, MD,[7] Kathryn D. Wine, MPH,[7] Jonathan N. Sembrano, MD,[8] and the INSITE Study Group.

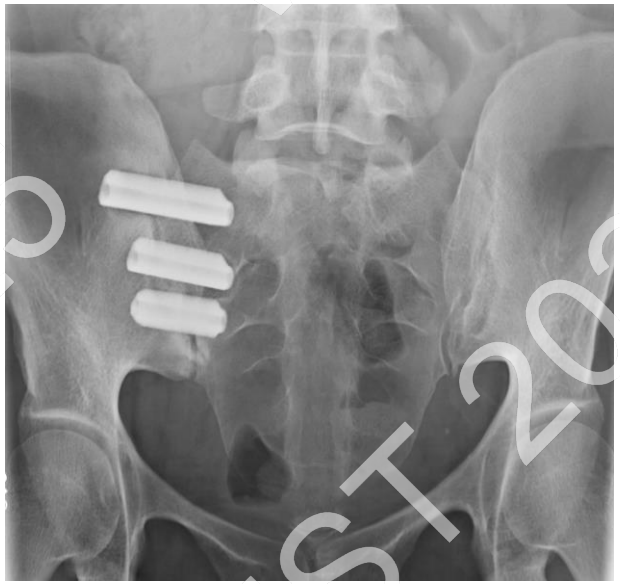
INSITE 2-year Results

		iFuse % subjects	NSM % subjects
Primary Endpoint *	Success @ 6 mo	82%	26%
Patient Satisfaction	Very or somewhat satisfied	90% (6 mo) 88% (2 yr)	61% (6 mo)
Clinical Improvement (Minimum Clinically Important Difference)	VAS improvement ≥ 20pt	83% (2 yr)	10% (2 yr)
	ODI improvement ≥ 15pt	68% (2 yr)	7.5% (2 yr)
Opioid Use	% change in number of subjects taking opioids	30% ↓ (baseline to 2 yr)	7.5% ↑ (baseline to 6 mo)

* Binary success/failure composite measure. Success if all criteria met: VAS SI joint pain reduction ≥ 20 points, no device-related SAEs, no neurological worsening, and no surgical re-intervention for SI joint pain.

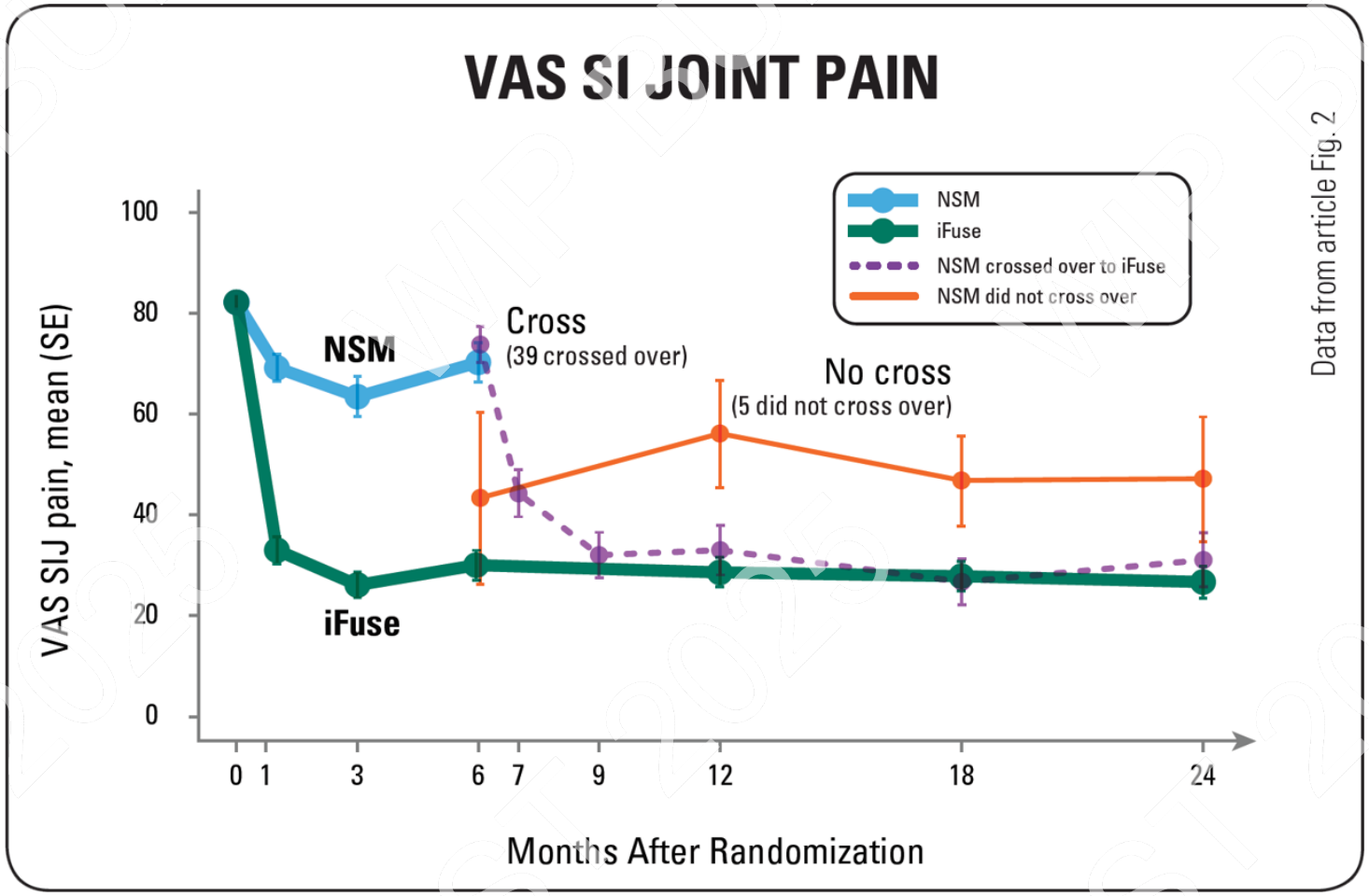
Polly – *Int J Spine Surg* 2016 (INSITE 2yr)

50



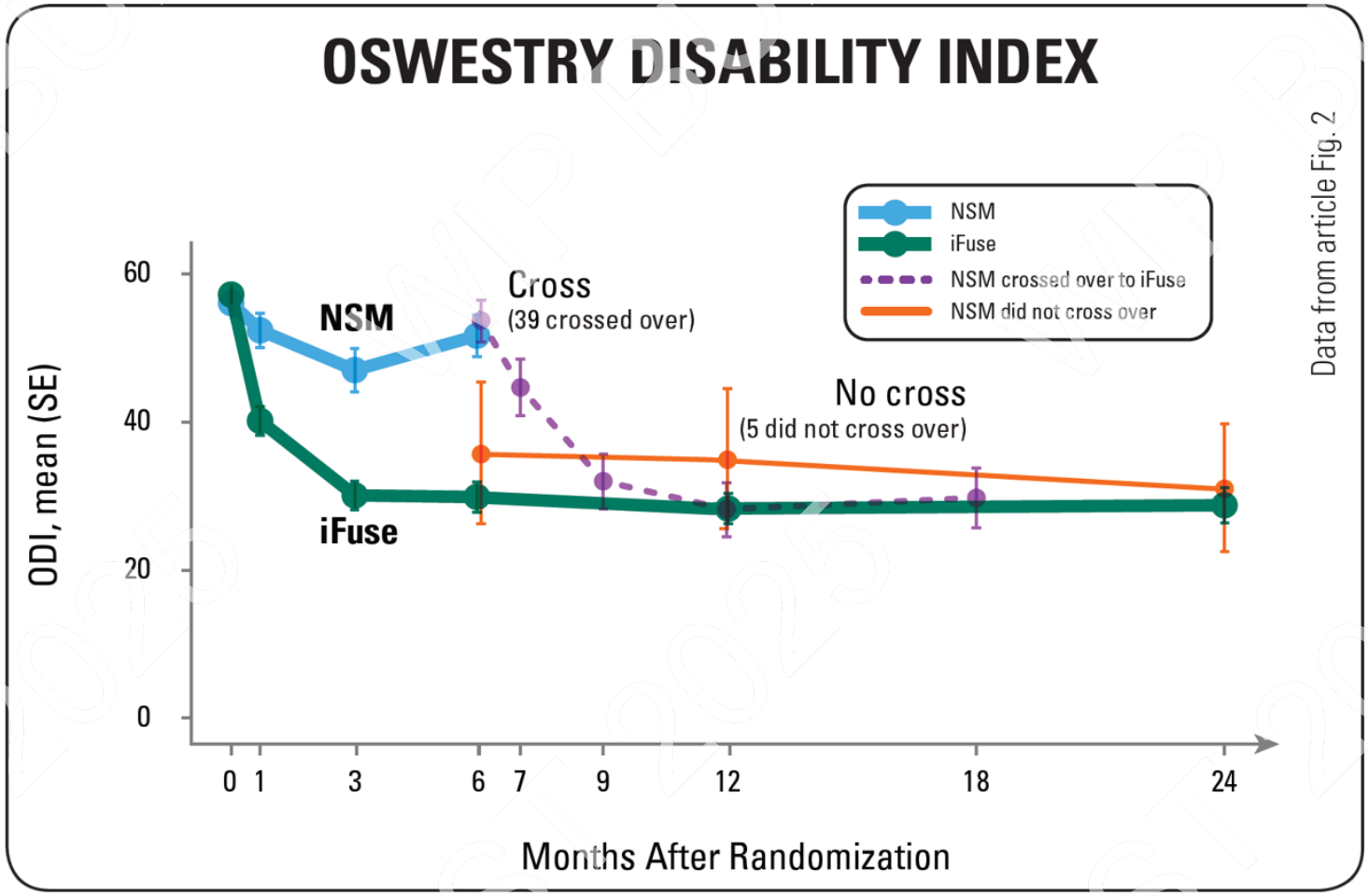
Polly et al. International J. Spine Surgery, 2016
www.SI-Bone.com

INSITE 2-year Results: VAS SI Joint Pain



Polly – *Int J Spine Surg* 2016 (INSITE 2yr)

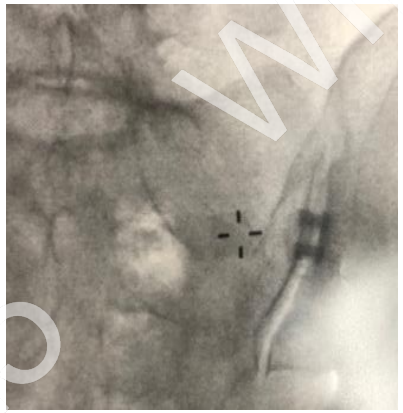
INSITE 2-year Results: Disability

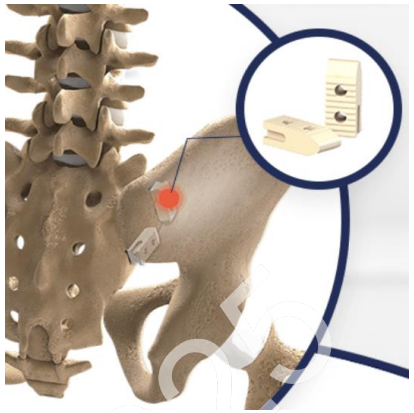


Polly – *Int J Spine Surg* 2016 (INSITE 2yr)

MIS Posterior SIJ Fusion: "New Kid on the Block"

- Minimally invasive
- Posterior intraarticular approach
- Outpatient, under sedation anesthesia
- Fluoroscopic guidance
- Bone allograft (no metallic implant)
- Less invasive option for SI stabilization
- Additional option in the spectrum of care
- Developing evidence





- Sacroiliac LinQ fusion: 20 patient case series' – Pyles *et al* FSIPP 2019
- Initial experience with MI SI Fusion device; retrospective case series' – Kim, et al ASRA 2019
- LinQ SI Fusion for pain relief in SCS patient: A case series' – Pyles, Sayed *et al* NANS 2020
- Multicenter outcomes in minimally invasive SI Fusion' Lam *et al* ASIPP 2020

Journal of Pain Research

Dovepress

ORIGINAL RESEARCH

Safety, Efficacy, and Durability of Outcomes: Results from SECURE: A Single Arm, Multicenter, Prospective, Clinical Study on a Minimally Invasive Posterior Sacroiliac Fusion Allograft Implant

Aaron Calodney[1], Nomen Azeem[2], Patrick Buchanan[3], Ioannis Skaribas[4], Ajay Antony[5], Christopher Kim[6], George Girardi[7], Chau Vu[8], Christopher Bovinet[9], Rainer Vogel[10], Sean Li[11], Navdeep Jassal[12], Youssef Josephson[13], Timothy Lubenow[14], Christopher M Lam[15], Timothy R Deer[6]

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Correspondence: Aaron Calodney, Precision Spine Care, Tyler, TX, USA, Email aaroncalodney@me.com

Introduction: Research suggests that sacroiliac joint (SIJ) dysfunction is responsible for 15% to 30% of reported low back pain cases. Recently, there has been an increasing interest in SIJ fusion using minimally invasive surgery (MIS) due to safety. Initially, devices designed for MIS were intended for lateral approaches. A minimally invasive sacroiliac fusion implant for use with a posterior approach has been developed and is regulated for clinical use under the regulatory framework required for human cells, tissues, or cellular or tissue-based products (HCT/Ps).

Methods: A multi-center, prospective, single-arm study was launched after initial studies provided preliminary data to support safety, efficacy, and durability of this minimally invasive sacroiliac posterior fusion LinQ allograft implant (NCT04423120). Preliminary results were reported previously. Final results for the full participant cohort are presented here.

Results: One-hundred and fifty-nine (159) participants were enrolled across 16 investigational sites in the US between January 2020 and March 2022. One-hundred and twenty-two (122) participants were implanted. At the 1-month follow-up, 82 participants satisfied all criteria for the composite responder endpoint, representing 73.2% of the study cohort. These results stayed consistent across the remaining study timepoints with 66.0%, 74.4%, and 73.5% of participants classified as responders at the 3-, 6- and 12-month follow-up visits, respectively. VAS scores were significantly reduced ($p < 0.0001$) and ODI scores were significantly improved ($p < 0.0001$). All domains of the PROMIS-29 were also significantly improved (all p's <0.0001). Only one procedure-related serious AE was reported in the study.

Conclusion: These results suggest that the posterior approach LinQ Implant System is a safe and effective treatment for sacroiliac joint dysfunction at 12 months, with results that are favorable compared to outcomes reported for an FDA-cleared lateral approach.

Keywords: sacroiliac joint disease, sacroiliac fusion, single point posterior fusion, back pain, minimally invasive spine surgery, sacroiliitis

Introduction

Low back pain continues to be an escalating cause of disability on both a national and international scale. The Lancet published a study in 2017 that examined the incidence, prevalence, and years lived with disability for 328 diseases in 195 countries. This study found that low back pain accounted for over 57 million years of living with disability, representing an 18% increase from 2006 to 2016 in the countries surveyed.[1] Research suggests that sacroiliac joint (SIJ) dysfunction is responsible for 15% to 30% of reported low back pain cases.[2–4] Traditional SIJ dysfunction treatments involve medications, therapy, injections, and ablations.[3] In cases where these methods fail, surgical fixation is considered.

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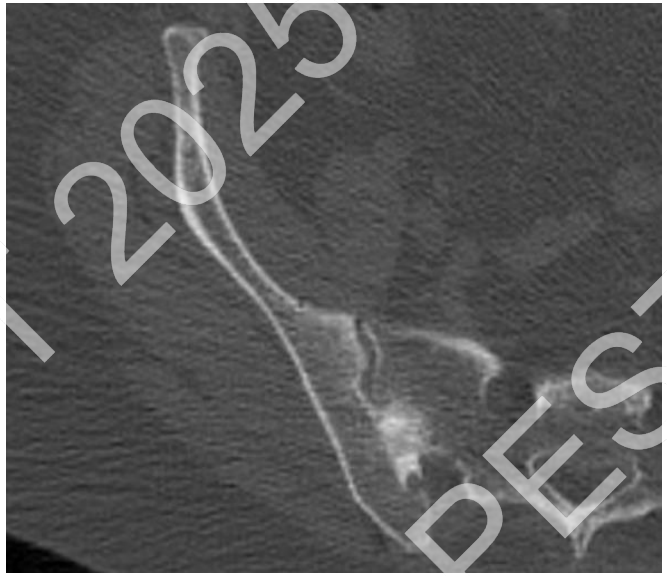
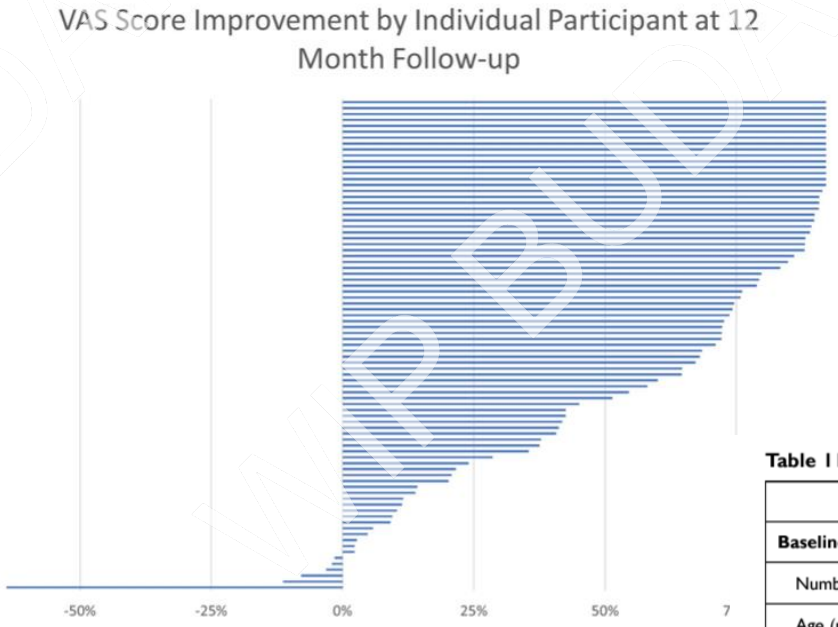
A.K. Calodney et al. 2022

SECURE

A Single arm, MulticEnter, Prospective, Clinical StUdy on a Novel Minimally Invasive PosterioR Sacroiliac Fusion DEvice

- Multi-center, prospective single arm clinical trial
- N=83 patients, at 12-months
- 73.5% > 20mm (compared to INSITE study)
- 61.4% > 50% improvement from baseline
- 34.9% > 80% improvement from baseline
- Non-inferior to lateral SI joint fusion
- Improvement in VAS and ODI
- SAE
  - LinQ: 4
  - INSITE: 22





SECURE

A Single arm, MulticEnter, Prospective, Clinical StUdy on a Novel Minimally Invasive PosterioR Sacroiliac Fusion DEvice

Table 11 SECURE, iMIA and INSITE Study Data Comparison at 12 Months

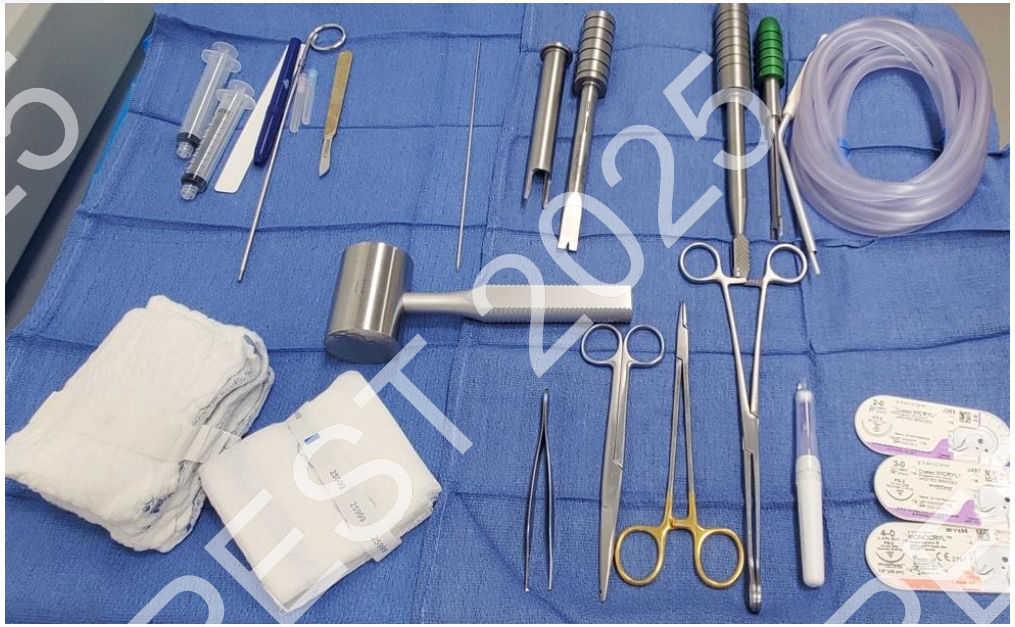
	SECURE	Imia[a,b]	INSITE[c,d]
Baseline Characteristics			
Number of participants with available data	84	52	98
Age (mean) in years, mean (SD)	59.0 (9.8)	49.4	50.2 (11.4)
Female, n (%)	82 (70.1%)	38 (73.1%)	75 (73.5%)
Body Mass Index (BMI), mean (SD)	30.3 (5.8)	26.5	30.3 (6.4)
Duration of Pain in years, mean (SD)	5.8 (7.0)	4.9	7.0
VAS Scores for SIJ pain, mean (SD)	76.2 (13.1)	77.7 (11.3)	82.3 (11.9)
Oswestry Disability Index (ODI), mean (SD)	52.4 (12.4)	57.5 (14.4)	57.2 (12.8)
Surgical Characteristics			
Right side, n (%)	59 (50.4%)	Not reported	55 (53.9%)
Bilateral, n (%)	8 (6.8%)	7	26 (25.4%)
Fluoroscopy time (in minutes), mean (SD)	1.6 (1.8)	2.1	2.5 (3.6)
Hospital length of stay (in days), mean (SD)	0	3	0.78
Anesthesia Type			
MAC, n (%)	87 (74.4%)	0 (0%)	0 (0%)
General, n (%)	18 (15.4%)	49 (100%)	98 (100%)
Local, n (%)	8 (6.8%)	0 (0%)	0 (0%)
Sedation, n (%)	4 (3.4%)	0 (0%)	0 (0%)

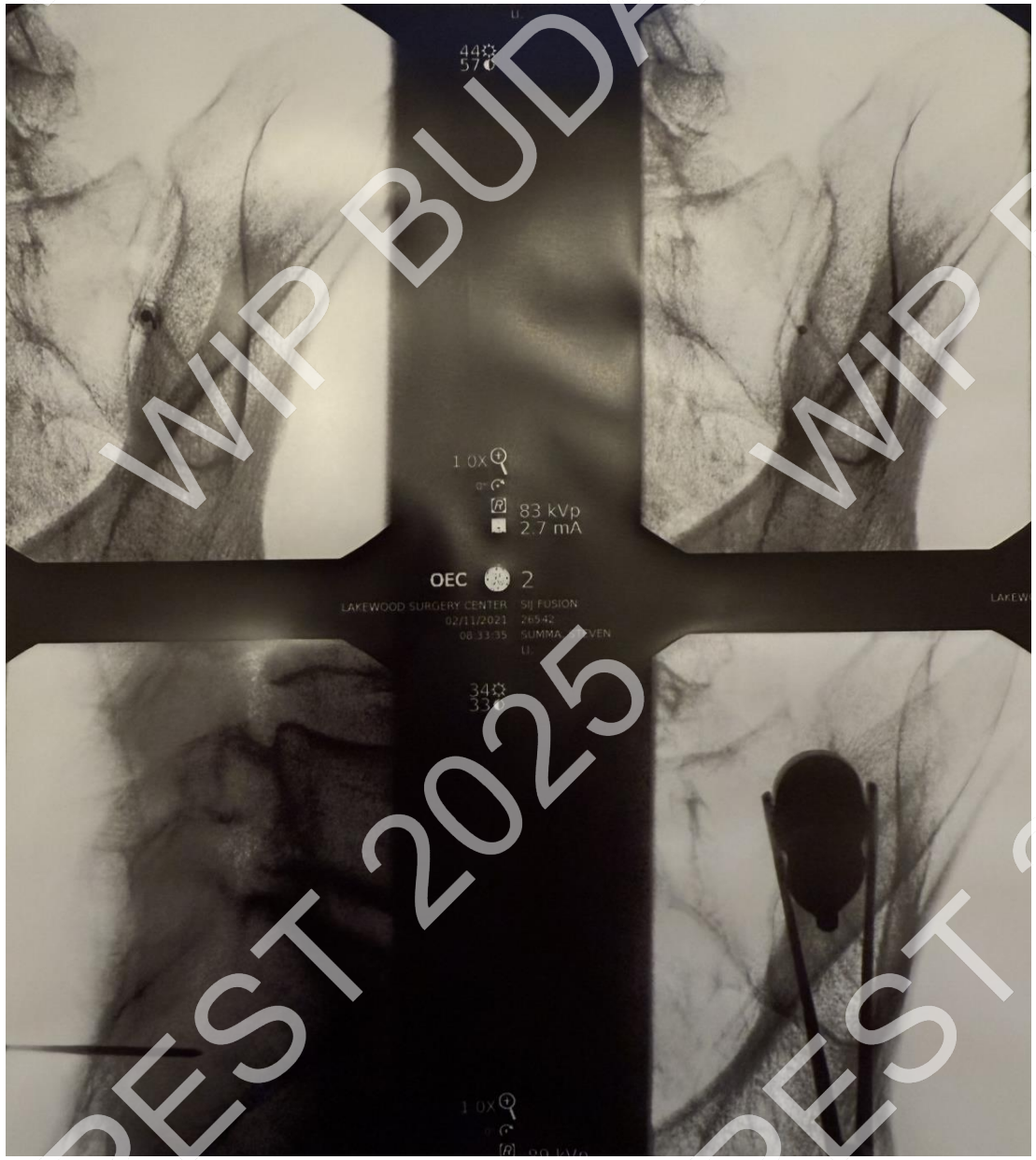
Table 11 (Continued).

	SECURE	Imia[a,b]	INSITE[c,d]
VAS Scores			
Baseline, mean (SD)	76.2 (13.1)	77.7 (11.3)	82.3 (11.9)
12-Month, mean (SD)	32.6 (27.9)	35.2 (25.5)	28.3
Average improvement, mean (SD) (p-value < 0.001)	43.3 (29.1)	41.6 (27.0)	54.2
Improvement ≥ 20 mm, n (%)	61 (73.5%)	Not reported	80 (81.6%)
ODI Scores			
Baseline percentile, mean (SD)	52.4 (12.4)	57.5 (14.4)	57.2 (12.8)
Average improvement, mean (SD) (p-value < 0.001)	25.3 (21.3)	25.0	29.3
Improvement ≥ 15, n (%)	57 (68.7%)	Not reported	71 (72.4%)
12-Month, mean (SD)	26.9 (18.3)	32.1 (19.9)	28.1
Adverse Events			
Total AEs	5	17[e]	179[e]
SAEs	4	8	22
Implant-related SAEs	0	0	2
Implant and/or procedure-related AEs	1	2[f]	18

- Posterior intraarticular approach
- Similar approach as SI joint injection
- Under sedation anesthesia
- Guide pin followed by serial dilation
- Decortication
- Deploy bone graft

www.painteq.com, courtesy of PainTeq





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EXPERT OPINION

A Review and Algorithm in the Diagnosis and Treatment of Sacroiliac Joint Pain

This article was published in the following Dove Press journal:
Journal of Pain Research

Steven Falowski[1]
Dawood Sayed[2]
Jason Pope[3]
Denis Patterson[4]
Michael Fishman[5]
Mayank Gupta[6]
Pankaj Mehta[7]

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Introduction: The sacroiliac joint (SIJ) has been estimated to contribute to pain in as much as 38% of cases of lower back pain. There are no clear diagnostic or treatment pathways. This article seeks to establish a clearer pathway and algorithm for treating patients.

Methods: The literature was reviewed in order to review the biomechanics, as well as establish the various diagnostic and treatment options. Diagnostic factors addressed include etiology, history, physical exam, and imaging studies. Treatment options reviewed include conservative measures, as well as interventional and surgical options.

Results: Proposed criteria for diagnosis of sacroiliac joint dysfunction can include pain in the area of the sacroiliac joint, reproducible pain with provocative maneuvers, and pain relief with a local anesthetic injection into the SIJ. Conventional non-surgical therapies such as medications, physical therapy, radiofrequency denervation, and direct SI joint injections may have some limited durability in therapeutic benefit. Surgical fixation can be by a lateral or posterior/posterior oblique approach with the literature supporting minimally invasive options for improving pain and function and maintaining a low adverse event profile.

Conclusion: SIJ pain is felt to be an underdiagnosed and undertreated element of LBP. There is an emerging disconnect between the growing incidence of diagnosed SI pathology and underwhelming treatment efficacy of medical treatment. This has led to an increase in SI joint fixation. We have created a clearer diagnostic and treatment pathway to establish an algorithm for patients that can include conservative measures and interventional techniques once the diagnosis is identified.

Keywords: sacroiliac joint, SIJ pain, sacroiliac joint dysfunction, sacroiliitis, sacroiliac joint fusion

Introduction

Low back pain (LBP) is among the most common human health problems, with a global point prevalence of 9.4%, yearly prevalence of 38%, and accounting for half of years lived with disability (YLD) due to a musculoskeletal disorder worldwide.[1] Chronic low back pain (cLBP) is a complex biopsychosocial condition in which recurrent back pain with or without clear pathology leads to chronic pain, physical dysfunction, social isolation, and/or mood changes.[2] It is challenging to treat a nonspecific condition and even more difficult to treat symptoms without an accurate diagnosis to allow for source control.

The sacroiliac joint (SIJ) is a large, irregularly shaped, serpentine joint structure bordered anteriorly and posteriorly by the sacroiliac ligaments. The joint itself is about two-thirds synovial and one-third ligamentous, with the synovial portion extending anteroinferiorly and reinforced at its posterosuperior aspect by syndesmotic ligament.[3]

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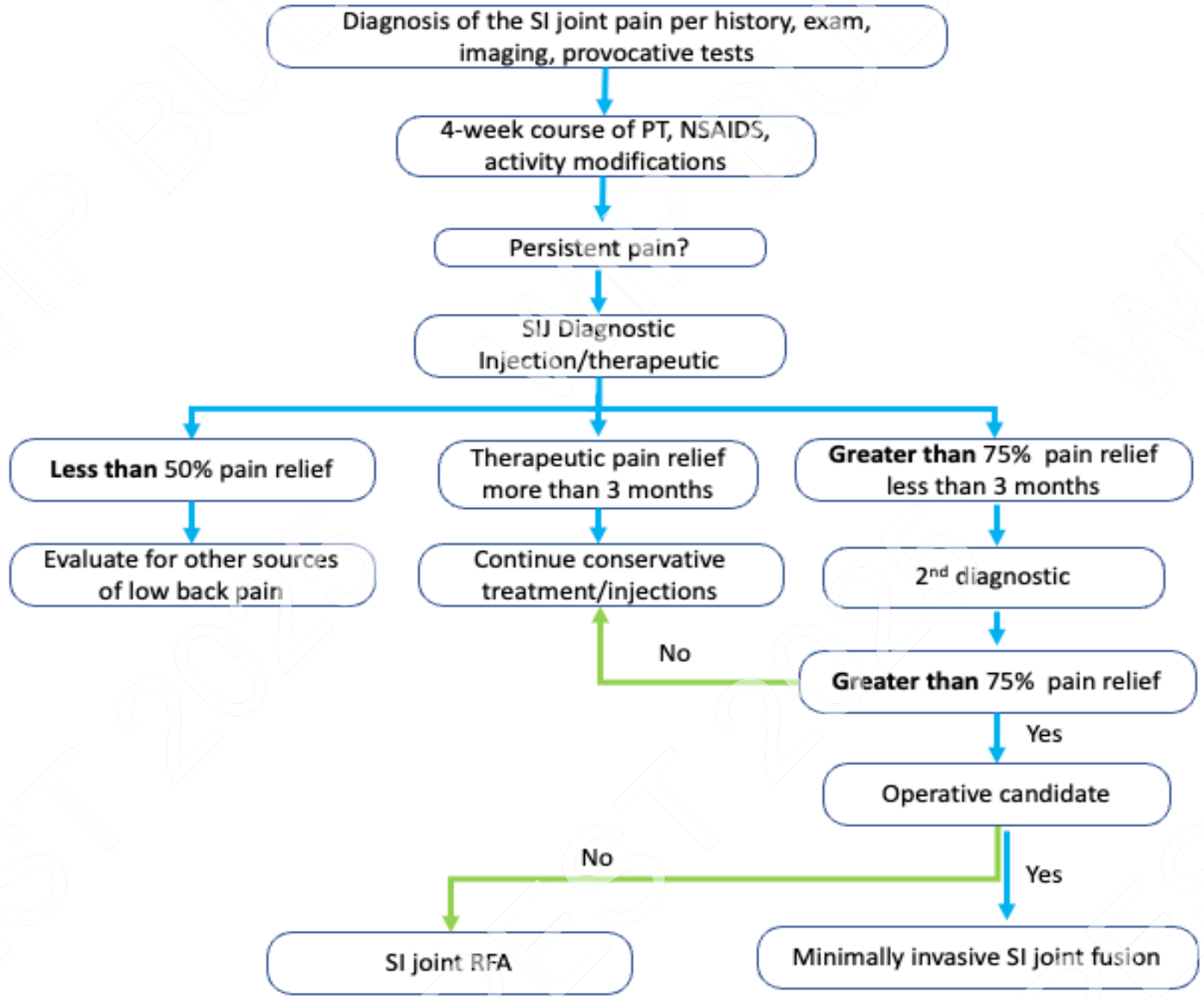
Sacroiliac Joint Dysfunction Algorithm For The Interventionalist



Summary

- SIJ pain is a common chronic pain condition, 15-30% of LBP
- Increased attention due to association with FBSS
- Heterogeneous nature of SIJ pain
- Lack of “gold standards” for diagnosis and treatment
- Steroid injections provide short term pain relief
- RF provides safe effective pain relief, 6-12 months
- Emerging treatment options PNS, MIS lateral and posterior fusion
- Reimbursement challenges pending further evidence

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