Diagnosis and Treatment of the Sacroiliac Joint
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Practice:
Injured Reserve!
Speaker Specific Disclosures:

- The speaker received no compensation for this presentation.
- Paid consultant of SI-BONE, Inc.
- Conducts clinical research for SI-BONE, Inc.
Program Objectives

1. Prevalence of SI Joint Pain
2. Biomechanics & Anatomy Review
3. Standard Protocol for SI Joint Diagnosis Based On:
   - Physical Exam
   - Provocative Testing
   - SI Joint Injection
4. SI Joint Surgery
5. Review Clinical Results
6. Reimbursement Overview
Fortin Finger Test

Where does it hurt in a patient with SI joint pain?

“Right Here Doc”
Anatomy

Sacroiliac Joint
Anatomy

Lateral Sacrum

- Sacral Promontory
- Ala
- Interosseous Ligament (posterior)
- SI joint Articular Surface (anterior)
Prevalence of SI Joint Pain
Prevalence of SI Joint Pain

15-30%
Component of chronic LBP

32-43%
Symptomatic Post-Lumbar Fusion

Bernard 1987
32%
Katz 2003

Schwarzer 1995
35%
Maigne 2005

Maigne 1996
43%
DePalma 2011

Irwin 2007
32%
Katz 2003

Sembrano 2009
40%
Liliang 2011

DePalma – Pain Med 2011
Prevalence of Work-Related SIJ Patients

42%  Bernard 1997
    Compensable Injury = Worker’s Comp

45%  Dreyfuss 1996
    38 of 85 patients

42%  Schwarzer 1995

Adjacent Segment Degeneration

75% of post-lumbar fusion patients showed SI joint degenerative changes on CT scan 5 years after vs. only 38% age- and gender-matched controls without prior lumbar fusion

Lumbar fusion leads to increases in angular motion and joint stress at the SI joint

1. Ha – Spine 2008
2. Ivanov – Spine 2009
Higher Prevalence of SI Joint Pain in Females

Approximately 2/3 of patients with SI Joint Dysfunction are women*

Pregnancy-related Pelvic Girdle Pain (PPGP)

- 45% of pregnant women have lower back and/or pelvic pain\(^1\)
- 25% of pregnant women report severe pain\(^1\)
- 5% of ALL pregnant women had pain 3 years later \(^2\)

* Based on multiple prevalence and treatment studies:

1. Wu – Eur Spine J 2004
Differential Diagnosis: Shooting at the Right Target

Multiple Possible Pain Generators

Lumbar Spine  SI Joint  Hip
Diagnostic Algorithm

Presentation & History

Physical Exam (Lumbar, SI Joint, Hip)

Positive Fortin Finger

Positive Provocative Tests

Positive Intra-articular SI joint Diagnostic Block(s)
Differential Diagnosis, Physical Exam: Hip, SIJ, Lumbar

LUMBAR SPINE
- Range of Motion: Forward flexion, extension, lateral flexion, rotation, combination
- Neuro Exam
  - Motor, Sensory, Deep Tendon Reflexes (DTRs)
  - Dural tension tests

SI JOINT
- Palpation
  - PSIS
  - Iliac crest
  - Dorsal Ligament
  - Sacral Sulcus
- Provocative Tests
- Active Straight Leg Raise (ASLR)

HIP and PELVIS
- Range of Motion: Flexion, extension, internal / external rotation
- Scour Test: (loaded circumduction)
- Gait evaluation
- Palpation: Piriformis, trochanteric area
**History and Complaints**

<table>
<thead>
<tr>
<th>HISTORY</th>
<th>COMPLAINTS</th>
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</table>
| **When did the pain start?** | **•** Lower back pain  
**•** Sensation of numbness, tingling or weakness  
**•** Pelvis / buttock pain  
**•** Hip / groin pain  
**•** Feeling of leg instability, buckling, or giving way  
**•** Disturbed sleep patterns  
**•** Disturbed sitting patterns (unable to sit for long periods, on one side)  
**•** Pain going from sitting to standing |
| • Prior trauma (examples)  
  – A fall on the buttock  
  – Car accident  
    (T-bone, rear-end, head-on)  
  – Lift/Twist  
  – Other  
• Prior lumbar fusion  
  – Prior iliac bone graft harvest  
• Pregnancy |
SI Joint Pain Presentation

Pain Diagram

- Pain in buttock and posterior thigh
  - Usually not midline
  - Usually below L5
  - At or lateral to PSIS
  - Occasionally groin
- Secondary pain in lateral thigh, groin, and/or lateral calf

Fortin – Spine 1994
Potential Causes of SIJ Pain: Traumatic

- MVA: Foot on Brake
- Slip and Fall
- Lifting and Twisting
- Traction Injuries
Potential Causes of SIJ Pain: *Gradual Onset*

- **Laxity of the SIJ / Multiple Pregnancies**
- **Repetitive Forces on SIJ and Supporting Structures**
- **Biomechanical Abnormalities**
  - Leg Length Inequality
  - Pelvic Obliquity/Scoliosis
  - Iliac crest bone graft
- **Arthritis**
- **Adjacent Segment Degeneration**
  - After Lumbar Spinal Fusion
- **Post Infection Degeneration**
Exacerbating Activities

Pain with Transitional Motions
• Supine to painful side
• Sit to stand
• Rolling over in bed
• Getting in /out of bed

Pain while Stationary
• Sitting on affected side
• Prolonged standing/sitting

Unilateral Weight Bearing
• Putting on Socks/Shoes
• Ascending/Descending Stairs
• Getting in and out of Car
• Prolonged Walking
  (85% of Gait is Single leg Stance)

Sexual Intercourse

Janda – Aust J Physiotherapy 1983
Relieving Activities

• Bearing weight on unaffected side
• Lying on unaffected side
• Manual or belt stabilization
Physical Exam
Fortin Finger Test

Point to pain while standing

• Able to localize pain with one finger
• Within 1 cm of PSIS (inferomedial)
• Consistent over at least 2 trials

Ask patient to point to location of primary pain

• Below L5: Consider SIJ
• Above L5: Consider lumbar spine etiologies

The following five provocative tests, when performed in combination, are proven to have a high degree of sensitivity and specificity:

1. Distraction* (Highest PPV**)
2. Thigh Thrust*
3. FABER
4. Compression*
5. Gaenslen’s Maneuver

* Most sensitive of tests
** PPV = positive predictive value

<table>
<thead>
<tr>
<th></th>
<th>Laslett(^1,2)</th>
<th>Szadek(^3)</th>
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<tbody>
<tr>
<td>3 or more positive tests</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sensitivity</td>
<td>91%</td>
<td>85%</td>
</tr>
<tr>
<td>Specificity</td>
<td>78%</td>
<td>76%</td>
</tr>
</tbody>
</table>

1. Laslett – *Man Ther* 2005
2. Laslett – *J Man Manip Ther* 2008
SI Joint Provocative Tests

- Distraction
- Compression
- Thigh Thrust
- Gaenslen
- FABER

3 of 5 positive tests provides discriminative power for diagnosing SI joint pain

Szadek – J Pain 2009
Laslett – J Man Manip Ther 2008
When to Proceed with SI Joint Injection

Positive History

Positive Fortin Finger Test and Physical Exam (Lumbar Spine, SI Joint, and Hip)

Positive Provocation Testing
What’s the Reference Standard for Diagnosis?

Diagnostic Injection
- Confirm with contrast and imaging
- Low volume, local anesthetic
- Pain Reduction for positive test*
  - ≥ 75% require per NASS Recommendations\(^2\)
  - ≥ 50% require per ISASS Guidelines\(^1\)
  - < 50% = maybe SIJ, but consider other pain sources

Therapeutic Injection
- Local anesthetic + corticosteroid
- May provide intermediate or long-term relief
- Results of can be unpredictable

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* Check payor policy for positive test criteria
Diagnostic Algorithm for SI Joint Pain

- **History & Presentation**
- **Physical Exam** (lumbar, SI, hip)
- **Provocative Tests**
- **Diagnostic Injections**

If **NO** significant positive clinical response:
- Other possible pain generator; Continue workup

If **YES** significant positive clinical response:
- **Treatment Options**
  - Medication(s), PT, SIJ Injections, RF Denervation, MIS SI Joint Fusion
Non-surgical Treatment Options

**Symptom Management**
- **Medications** (Non-steroidal anti-inflammatory drugs [NSAIDs], Oral Steroids & Pain Medications)
- External SI joint stabilization with belting
- Therapeutic SI Injections
- Radiofrequency Ablation (RFA)

**Physical Therapy** (Patient Specific)
- Motor control & core strength
- Restore normal functional movement patterns / proper gait
- Soft tissue mobilization
- Restore muscle length and balance
- Manual therapy (muscle energy techniques/ mobilization etc.)
- Modification of ADLs (Patient education on posture, body mechanics, positioning)

Sembrano – *Current Orthopedic Practice* 2011
Cohen – *Anesth Analg* 2005
Treatment Options: Surgical

Smith-Petersen 1926

Campbell 1927

Gaenslen 1927

Bloom 1937

iFuse 2008
iFuse Implant System®

• **Unique Patented Design**
  - Triangular shape (minimizes rotation)
  - Interference press fit (immediate fixation)
  - Porous titanium surface
    (promotes bony ongrowth/ingrowth for long-term fusion)*

• **Strength of Experience**
  27,000+ procedures worldwide (August 2017)

• **Clinical Evidence**
  - iFuse Implant is the **ONLY** device for treatment of SI joint dysfunction supported by multiple prospective clinical studies including 2 RCTs
  - More than **50** peer-reviewed publications

iFuse vs. Open

iFuse Provided Better **Operative Measures** vs. Open
- Shorter surgery time\(^1,2,3\)
- Less estimated blood loss\(^1,2\)
- Fewer days in the hospital\(^1,2,3\)

iFuse Provided Better **Clinical Outcomes** vs. Open
- Better pain relief (VAS) at 12 and 24 months\(^1\)
- Better disability improvement (ODI)\(^2,3\)

2. Ledonio – *Clin Orthop Relat Res* 2014
iFuse Procedure Overview

**Incision**
(~3 cm)

**Pin**

**Soft Tissue Protector**

**Measure**

**Drill**
(optional with sharp-tip broach)

**Broach**

**Insert Implant**

**Repeat**
(2 more times)
Post-Operative Considerations

Individual Treatment Plans

- Age
- Weight
- Bone Quality
- Associated health factors

Post Surgical Decisions

- Plan for protected weight bearing
- Activity limitations
- Post op rehab plans
- Plan for return to activity
Post-Operative Considerations

Eliminate Restrictions in Adjacent Structures
- Hip Capsule
- Lumbar and Thoracic Spine / Knee and Ankle Joints

Retraining of Functional Movement Patterns/Motor Control
- With Activities of Daily Living
- With Recreational Activities in Patient Population

Regain / Maintain Cardiovascular Health
Usual postoperative course:

Off work 2 weeks.

Limited duty at 2-6 weeks post op

Full Duty at 3 months

No permanent work restrictions

10% PPD based on comparable PPD for single level lumbar fusion
**Prospective Clinical Studies Overview**

**iMIA: iFuse Implant System® Minimally Invasive Arthrodesis**
- Multicenter, Prospective, RCT (EU)
- 103 patients enrolled, 9 sites, 4 countries
- 24mo follow-up
- iFuse vs. Conservative Management
- 1yr pub

**INSITE: Investigation of Sacroiliac Fusion Treatment**
- Multicenter, Prospective, RCT (USA)
- 148 patients enrolled & treated
- 19 sites, 24mo follow-up
- iFuse vs. Non-surgical Management
- 2yr pub

**SIFI: Sacroiliac Joint Fusion with iFuse Implant System**
- Multicenter, Prospective, Single-arm
- 172 patients enrolled & treated
- 26 sites, 24mo follow-up
- First prospective study with iFuse Implant System
- 2yr pub

**LOIS: Long-Term Follow-up in INSITE/SIFI**
- Extended follow-up for INSITE and SIFI to 5 years
- Measuring safety and effectiveness
- In Progress; 100+ enrolled (3yr results submitted)
INSITE: Study Design

R = Randomization, 2:1 fashion to either MIS SI Joint Fusion or Non-surgical Management

* SI joint dysfunction due to sacroiliac joint disruption and degenerative sacroiliitis
INSITE 2-year Results
Improves more after SI joint fusion than NSM

VAS SI JOINT PAIN

Data from article Fig. 2

INSITE 2-year Results:
Improves more after SI joint fusion than NSM
Adverse Events per Subject Frequency (first 180 days)

1.5 iFuse vs. 1.3 NSM per subject (p=0.2253)

Device- or Procedure-Related Adverse Event

22 events: neuropathy (1), urinary retention (1), nausea/vomiting (2), atrial fibrillation (1), ipsilateral or contralateral SIJ pain and trochanteric bursitis (9), surgical wound problems (5), iliac fracture (1) and asymptomatic physical exam or radiographic findings (2).

Revision Surgery

3 iFuse subjects (3%) had a revision surgery through 2 years.
INSITE: Summary

Superior Outcomes

iFuse superior to NSM for chronic SI joint pain at 6 months
- Pain VAS, 53 vs. 12-point decrease (iFuse vs. NSM)
- Back Function ODI, 30 vs. 5-point decrease (iFuse vs. NSM)

Sustained Improvement at 2 years

iFuse provided rapid & sustained 2-yr clinical improvement
- Pain VAS, mean 55-point decrease at 2 years
- Back Function ODI, mean 28-point decrease at 2 years
- Quality of Life SF-36 and EQ-5D, improvement in all measures
- Satisfaction 88% very/somewhat satisfied at 2 years

Opioid Reduction

30% fewer iFuse treated patients taking opioids (baseline to 2 yr)

Low Revisions

3% revision rate (only 3 iFuse subjects had revision surgery by 2 years)

iMIA 1-year Results

Improves more after iFuse than CM

Mean change from baseline to 1 year

<table>
<thead>
<tr>
<th></th>
<th>VAS LBP</th>
<th>ODI</th>
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<tbody>
<tr>
<td>iFuse</td>
<td>-42</td>
<td>-26</td>
</tr>
<tr>
<td>CM</td>
<td>-14</td>
<td>-8</td>
</tr>
</tbody>
</table>

Dengler – Pain Physician 2017
SIFI 2-year Results
Prospective, Multicenter

- Sustained clinical outcomes (VAS, ODI)
- Radiographs show high rate (97%) of bony apposition (on at least 2 implants on both the iliac and sacral sides)

![Graphs showing VAS SI Joint Pain and ODI improvements over 2 years](image)

INSITE, iMIA, SIFI
Consistent Prospective Study Results

Graphs using data from:
iMIA 24mo data as of August 17, 2017 (publication in progress)
Polly – Int J Spine Surg 2016 (INSITE 2yr)
Duhon – Int J Spine Surg 2016 (SIFI 2yr)
CM, RF, SI Joint Fusion (iFuse)
6-Year Comparative Cohort Study

VAS SI Joint Pain

Conservative Management
SI Denervation
SI Joint Fusion (iFuse)

Baseline
6 months after infiltration
1 week after SI infiltration

Months Before / After Treatment

Vanaclocha – Neurosurgery 2017
Patients Back Working

- **Conservative Management**:
  - Baseline: 49%
  - Last Follow-up: 19%

- **Radiofrequency Ablation**:
  - Baseline: 49%
  - Last Follow-up: 34%

- **iFuse**:
  - Last Follow-up: 52%

Total:
- Baseline: 70%
- Last Follow-up: 52%

*Vanaclocha – Neurosurgery 2017*
**iFuse Patients Reduced Opioid Use**

2-year RCT
- 30% completely stopped opioid use

6-year Follow-up, 2 controls
- ONLY 7% long-term still on opioids

Conservative Care
- Baseline: 69%
- 1 mo: 63%
- 3 mo: 63%
- 6 mo: 48%
- 12 mo: 49%
- 18 mo: 55%
- 24 mo: 63%
- Last Follow-up: >80%

iFuse Implant™
- Baseline: 71%
- 1 mo: 69%
- 3 mo: 63%
- 6 mo: 63%
- 12 mo: 53%
- 18 mo: 49%
- 24 mo: 48%
- Last Follow-up: 7%


Vanaclocha – *Neurosurgery* 2017
SI Joint Pain

Rapid and Sustained Pain Relief – VAS SI Joint Pain

Complete References in Bibliography
Disability

Reduction in Disability – Oswestry Disability Index

Complete References in Bibliography
Satisfaction

High Patient Satisfaction

Patient satisfaction 91%
Average

Complete References in Bibliography
4-yr Revision Rate Study

11,388 patients (Apr 2009 – Aug 2014)

- 3.5% cumulative 4-yr revision rate
  (96.5% free from revision, a.k.a. survivorship)*
- Rate decreased annually since 2009
- Revision rate did not differ by age (< or > 65) or sex

4-year Cumulative Revision Rate Comparison

<table>
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<tr>
<th>Rate</th>
<th>Procedure</th>
<th>References</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.5%</td>
<td>iFuse, MIS SIJ Fusion</td>
<td>Cher – <em>MDER 2015</em></td>
</tr>
<tr>
<td>10-12%</td>
<td>Lumbar Decompression</td>
<td>Deyo – <em>JBJS Am 2011</em></td>
</tr>
<tr>
<td>12-14%</td>
<td>Lumbar Fusion</td>
<td>Martin – <em>Spine 2007</em></td>
</tr>
</tbody>
</table>

* iFuse Implant System Overall Revision Rate (August 2017)

Nationwide Medicare Coverage of MIS SIJ Fusion

8 Medicare Administrative Contractors (MACs)
Commercial Coverage

(Status as of August 2017)

iFuse Exclusive Policies

selecthealth

Geisinger Health Plan

HCSC Health Care Service Corporation

BlueCross BlueShield of Illinois

BlueCross BlueShield of Montana

Blue Cross and Blue Shield of New Mexico

BlueCross BlueShield of Oklahoma

BlueCross BlueShield of Texas

Blue Cross Blue Shield of Michigan

Blue Cross Blue Shield of Vermont

Health New England

California & North West

Kaiser Permanente

Kern Health Systems

Highmark

Priority Health

TRICARE

UnitedHealthcare

(case-by-case)
Coverage for **MIS SI joint fusion is recommended** for appropriately selected patients by the professional medical societies listed below. Patient selection criteria and recommendations for insurance coverage, can be accessed via the links below.

**North American Spine Society (NASS)**
The coverage recommendation outlines 8 criteria specifically intended to ensure patients are appropriately selected for the procedure. (June 2015)

**International Society for the Advancement of Spine Surgery (ISASS)**
ISASS has concluded that minimally invasive SI joint fusion is now the standard of care for a select subset of patients. ISASS concludes that minimally invasive SI joint fusion is a safe and effective procedure for patients with unremitting pain due to SI joint disorders. (Updated July 2016)
### 1. Comprehensive History

- **Date of onset**
- **Mechanism of onset**
- **Aggravating/relieving actions**
- **Location, type, of pain**
- **Functional limitations**
  - Walking, standing, sitting, stairs, lifting, etc.
- **Relevant history**
  - Prior lumbar fusion, trauma, LBP with pregnancy, inflammatory arthropathy, scoliosis, leg length inequality, etc.

### 2. Treatment to date (Include details)

- **Treating physicians** (duration, type, results)
- **Non surgical treatments**
  - Medications, Physical Therapy, Chiropractic, etc.
- **Injections/Procedures** – amount and duration of relief
  - Therapeutic Injections
  - RF Ablation
  - other
3. Diagnostic Imaging and Studies (Spine, Pelvis, Hip, etc.)
   - Study performed (e.g., CT Pelvis), date performed
     • Radiographic interpretation, key points, include report
     • Personal review / interpretation, describe SI joint findings
   - EMG/NCV reports

4. Physical Examination
   - Spine: inspection, palpation, ROM, neurologic exam
   - Pelvis: inspection, palpation (piriformis, trochanter, symphysis, etc.)
   - SI Joint: inspection, palpation, provocative maneuvers
   - Hip: inspection, palpation, ROM

5. Diagnostic Injection (date, dictated report, images, results)
   - Percentage of relief with injection
   - Duration of relief with injection
SI Joint Patient Resources

www.sijpc.org

- Patient Insurance Coverage Support (PICS)
- SI Buddy Program™
- Videos and other SI joint information

Call toll free (844) 742-8339 (844-SI-BUDDY)
SI Joint Patient Community and the SI Buddy℠ Program

If you are interested in connecting your patients who are considering the iFuse Procedure™ with an SI Buddy, or if you have a successfully treated iFuse patient interested in becoming an SI Buddy, have the patient contact us today!

• SI Buddy volunteers have all had the iFuse Implant System and are at least six-month post-operative.

• SI Buddy participants want to support others who suffer with SI joint pain by sharing their personal story.

www.sijpc.org

The SI Buddy program is reserved for patients who have been diagnosed by a trained surgeon and recommended for the iFuse procedure. SI Buddy volunteers have been successfully treated with the iFuse Implant System®. They are not medical professionals and their statements should not be interpreted as medical advice.
This reimbursement information is provided for convenience only. It is neither legal advice nor official payor guidance. SI-BONE does not warrant or guarantee that the use of the information will result in coverage or payment. Providers are solely responsible for determining medical necessity and for being in compliance with Medicare and other payor rules and requirements, as well as for the information they submit with claims and appeals. Before any claims or appeals are submitted, providers should review official payor instructions and requirements, confirm the accuracy of their coding or billing practices with these payors, and use independent judgment when selecting codes that most appropriately describe the services or supplies provided to a patient.
The iFuse Implant System is intended for sacroiliac fusion for conditions including sacroiliac joint dysfunction that is a direct result of sacroiliac joint disruption and degenerative sacroiliitis. This includes conditions whose symptoms began during pregnancy or in the peripartum period and have persisted postpartum for more than 6 months.

There are potential risks associated with the iFuse Implant System. It may not be appropriate for all patients and all patients may not benefit. For information about the risks, visit: www.si-bone.com/risks

One or more of the individuals named herein may be past or present SI-BONE employees, consultants, investors, clinical trial investigators, or grant recipients. Research described herein may have been supported in whole or in part by SI-BONE.
Thank You


References (alphabetically)


**Society Guidelines**


LEVEL I – Randomized Clinical Trial [7]


LEVEL II/IIb – Prospective, Multicenter [6]


LEVEL III – Clinical Comparisons [5]


LEVEL IV – Clinical [17]


LEVEL IV – Clinical [17] (cont.)


REVIEWS [3]


ECONOMICS [5]

- Polly DW, Cher D. Ignoring the sacroiliac joint in chronic low back pain is costly. Clinicoecon Outcomes Res. 2016;8:23–31. DOI: 10.2147/CEOR.S97345.

OTHER [7]

BIOMECHANICS [3]

