SI Joint Fusion for SI Joint Pain: To Fuse or Not to Fuse?

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Florida Orthopaedic Institute
Keys to Understanding

Understanding the anatomy and biomechanics_
  Why does it cause pain, why fusing will help, what happens next.

Prevalence of SI Joint pain
  Bernard, Schwarzer, Cohen, Weksler, Sembrano

Prevalence in post lumbar fusion patients
  Maigne, Ha, Ivanov, Liliang, DePalma

Differential Diagnosis
  Zelle

Clinical Results
  Historical and Ifuse (Sachs Rudolf)

Current Standard of Care
  iFuse Implant System
Why is SIJ Overlooked?

- Not part of standard physician training
- Not thought to be a true joint
  - Some think similar to pubic symphysis
- Very little movement in the joint
  - 2-4mm and 1-4 degrees of rotation
- SIJ pathology confused with other pain generators
- SIJ pathology often coexists with spine and hip pathology
- MRI scans do not go below the SIJ
- Not referred from physiatrist, IR’s, chiropractors, others
- No easy, less-invasive surgical solution (until now)
The Anatomy

- Ala
- Iliac Crest
- Ilium
- Pubic Bone
- Ischium
- Sacral Promontory
- Neural Foramen S1, S2, S3, S4
- Acetabulum
- Pubic Crest
The Anatomy

- Ala
- Sacral Promontory
- Neural Foramen S1, S2, S3, S4
- SIJ Articular Surface

S1, S2, S3, S4, S5
The Anatomy

- Sacral Promontory
- Ala
- SIJ Articular Surface
Anterior Ligaments

- Short strong ligaments indicative of allowing little movement and providing stability
Posterior Ligaments

- Short strong ligaments allowing little movement and providing stability
- Note: basket weave pattern for increased strength and stability
Ant & Post Shear Forces

Largest forces are Inferior

Sup

Infer

Cha
Primary motion is Nutation, which is a nodding type of motion.

The rotation is usually limited to 1-2 degrees for males and 2-4 degrees for females.

Sacroiliac Movements in the Sagittal Plane. (a) Nutation; (b) Counternutation; (1) Pelvic Inlet Closure with Nutation; (2) Pelvic Outlet ening with Nutation; (3) Pelvic Inlet Opening with Counternutation; (4) Pelvic Outlet Closure with Counternutation.
Biomechanics

Note, the highest stresses flow through the inferior portion of the SI joint, thereby the hardest bone is in this area.
Innervation
Understanding CT findings of SIJ can shear forces explain findings categories of patients:

- Aging or Dysfunctional
- Post Lum Fusion
- Post ICBG
- (We know how to Dx AS, JRA, Tumors, Infections)

Reiley Oct, 2012
Incidence of SI joint as a pain generator

- “22.6% of patients with reported LBP had SIJ pain”
  - Bernard & Kirkaldy-Willis, 1987
- “≤25% of LBP SIJ in origin, but diagnosis of SIJ disease frequently overlooked”
  - Cohen SP. Anesth & Analgesia 2005
- 30% incidence of SIJ pain in LBP patients
  - Schwarzer AC. Spine 1995
- 35% incidence of SIJ pain in LBP patients
  - Maigne JY. Spine 1996
- “≤25% of LBP patients have significant pain coming from their hip and/or SI Joints”
  - Sembrano & Polly, 2009
In a study of 1,293 patients with low back pain, 22.6% were diagnosed with sacroiliac joint syndrome.

Well-recognized syndromes (herniated nucleus pulposus and lateral spinal stenosis) occurred in 27.3% of cases. Less-recognized syndromes (SI joint and posterior joint syndromes) occurred in 44.6% of cases.

Coexisting lesions occurred in 33.5%, the most common combined syndromes include: posterior joint and SI joint as well as spondylolisthesis and SI joint.
43 consecutive patients with chronic low back pain maximal below L5-S1 were investigated with SI joint blocks

13 patients obtained gratifying relief of their pain, 30%

9 of these exhibited tears of their ventral capsule

- Ventral Capsular Tears = Disruption
- Intra-articular sacroiliac joint injections
- Leakage observed on arthrography
- Prevalence: 69%
Consecutive case series evaluation of 200 LBP patients in a single spine surgery practice.

Pt’s with LBP: up to 25% of patients may have significant pain contribution from the hip or SI joints.

Findings: SI joint is a significant pain generator in 14.5% of LBP patients is very similar to the 18.5% and 13% to 30% findings other studies.
The SI joint can play a significant role in pain persisting after lumbar fusion.

Sacroiliac anesthetic blocks are considered the gold standard for the diagnosis of sacroiliac syndrome.

Study shows that, within a selected population with post-fusion low back pain, the SI joint is the likely source of pain in 35% of cases.
Prospective CT imaging assessment of the SI Joint was used to demonstrate degeneration of the SI joint in post-lumbar fusion patients.

SI joint degeneration at 5 years post-fusion

- Significantly higher vs. non-fusion group, 38.2%.

In one-segment fusion

- 91% developed SI joint degeneration.

In two-segment fusions

- 67% developed SI joint degeneration.

Regardless of whether the fusion includes the sacrum, the SIJ is influenced by increased mechanical stress arising from lumbar/lumbosacral fusion.
A finite element model of the lumbar spine-pelvis was used to simulate the posterior fusion at L4-L5, L4-S1, and L5-S1 levels, and assess motion at the SI joint.

Prevalence of SI joint involvement in post fusion low back pain ranges from 29% - 40%.

The results of the study indicate that posterior fusion of the lumbar spine leads to increase of motions at the SI joint and increase of stresses across SI joint articular surfaces.
52/130 (40%) post-fusion patients had 3 positive provocative tests for SIJ.

21/52 (40%) patients with symptoms suggestive of SIJ dysfunction had SIJ pain based on diagnostic blocks.

17 pts had 2 positive diagnostic SIJ blocks.

4 pts had 2/3 positive diagnostic SIJ blocks.

2/3 of patients had post-op pain that was characterized as ‘different’ from pre-op pain.

SIJ pain is a potential source of pain after lumbar and lumbosacral fusion surgeries.
12/28 (43%) of post-lumbosacral fusion patients were symptomatic for SIJ dysfunction based on diagnostic blocks (SI joint injections).

Prevalence range of SIJ pain in post-lumbosacral fusion patients was 43-61%.

In patients’ recalcitrant to non-interventional care, the sacroiliac joint is the most likely source of low back pain after lumbar fusion.
Differential Diagnosis:
Shooting at the Right Target

Multiple possible pain generators

Lumbar Spine  SI Joint  Hip
Differential Diagnosis: Rule out Lumbar Spine

Premise: Pain is coming from lumbar spine until proven otherwise

- Compressed nerve
- Stenosis: central, lateral recess, foraminal
- Herniated nucleus pulposus
- Disc damage, annulus tear
- Lumbar instability (Spondylolisthesis)
- Facet
Differential Diagnosis: Rule out the Hip

Premise: Pain may be coming from the hip!

Possible Hip Conditions:
- Labral tear
- Chondral pathology
- Ligamentum teres injury
- AVN, Occult fracture, DJD
- Pre-arthritic hip conditions (FAI)

Work Up:
- MRI Sensitive for hip pathology
- Differential Diagnostic injections
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

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 (22)

Sexual Intercourse

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

Relieving Activities

- Bearing weight on unaffected side
- Lying on unaffected side
- Manual or belt stabilization
Diagnosis

Complaints

- Lower Back Pain (LBP) below L5
- Pelvis/buttock pain
- Hip/groin pain
- Lower extremity pain (numbness, tingling, weakness)
- Disturbed sleep patterns
- Disturbed sitting patterns
- Unilateral leg instability

Describe Pain

- Pain diagram showing pain patterns centered on the SI joint and radiating down the leg (often unilateral)
Patient History

- New onset of chronic LBP +/- trauma
- Temporal relationship to post partum
- A fall on the buttock
- MVA; T-bone, rear end, head on
- Lift/Twist
- Prior lumbar fusion surgery
- Iliac crest bone graft
- Structural abnormalities, scoliosis etc.
- Inflammatory arthritis
- Treatments to date
SI Joint Examination

- Differential Diagnosis – spine, hip, SI joint
- Imaging
  - Imaging can be helpful to corroborating pathologies, but is not itself conclusive of pain generation
- Provocative Tests
- SI Injection is the gold standard
  - But must be done right...
Provocative Tests

- Faber
- Compression
- Thigh Thrust
- Gaenslen
- Distraction

• 3 of 5 must be positive (Thigh Thrust, Compression, Gaenslen, FABER, Distraction)
• 1 of 3 positive results must be Thigh Thrust or Compression
A reliable examination technique to identify the sacroiliac joint as a source of low back pain seems to be pain relief following a radiologically guided injection of a local anesthetic into the sacroiliac joint.

“The anti-inflammatory effect of injection therapy is not permanent, and the injections do not offer an opportunity to stabilize an incompetent joint.”

Patients who do not respond to non-operative treatment should be considered for operative sacroiliac joint stabilization.
Treatment

- Injections
- Radiofrequency ablation
- Fusion
Diagnostic Algorithm for SI Joint Pain

History

Physical Exam

Provocative Tests

Diagnostic Injections

Significant Positive Clinical Response?

YES

Treatment Options
Medication(s), PT, SIJ Injections, RF Denervation, MIS SI Joint Fusion

NO

Other possible pain generator; Continue workup
SI joint Arthrogram/Injection

- Diagnostic
- Therapeutic
- 40% patients receive long term benefit
Radiofrequency ablation

Significant ($p \leq 0.05$) improvement occurred in the following SF-36 categories: physical functioning, role physical, bodily pain, vitality, social functioning, role emotional, and neurogenic and pain indices.

For carefully selected patients, sacroiliac arthrodesis appears to be a safe, well tolerated, and successful procedure, leading to significant improvement in functional outcome and a high fusion rate.
Retrospective study of 50 consecutive patients

Single orthopedic spine surgeon in private practice

Initial clinical experience with implant and technique

Pain & satisfaction assessed preop & postop at 3-, 6-, 12-, and minimum 24-month follow-up (avg 40-months)

<table>
<thead>
<tr>
<th>Patients</th>
<th>50</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>54 (range 24-85)</td>
</tr>
<tr>
<td>Gender</td>
<td>34 F (68%), 16 M (32%)</td>
</tr>
<tr>
<td>Prior lumbar fusion</td>
<td>22 (44%)</td>
</tr>
<tr>
<td>Presence of lumbar pathology treated</td>
<td>8 (16%)</td>
</tr>
<tr>
<td>Non-surgically</td>
<td>—</td>
</tr>
</tbody>
</table>
Rudolf, 2012

Pain Scores
(How much pain are you in at this time?)

- Baseline: 7.6
- 3 Months: 3.68
- 6 Months: 3.24
- 12 Months: 3.31
- Avg 40 mo: 2.01
Rudolf, 2012

**CLINICALLY SIGNIFICANT IMPROVEMENT**

(>2 pt change in Pain Score)

<table>
<thead>
<tr>
<th>Time</th>
<th>Percent of Patients with Improvement</th>
</tr>
</thead>
<tbody>
<tr>
<td>3 Months</td>
<td>97%</td>
</tr>
<tr>
<td>6 Months</td>
<td>85%</td>
</tr>
<tr>
<td>12 Months</td>
<td>71%</td>
</tr>
<tr>
<td>Avg. 40 Months</td>
<td>82%</td>
</tr>
</tbody>
</table>
Rudolf, 2012

PATIENT SATISFACTION

(Would you have the same surgery again?)

PERCENT OF SATISFIED PATIENTS

- 91% at 3 Months
- 82% at 6 Months
- 82% at 12 Months
- 82% at Avg. 40 Months
Complications

Minor (5 patients, 10%)
- 3 patients w/ superficial cellulitis – treated with oral antibiotics
- 2 patients w/ hematoma – resolved over time

Intervention Required (5 patients, 10%)
- 1 patient w/ deep wound infection – treated with IV antibiotics
- 2 patients w/ S1 nerve root impingement – implant partially retracted
- 1 patient w/ L5 nerve root impingement – implant partially retracted
- 1 patient w/ SI joint pain 3 years post-op – additional implants placed
One year successful outcomes for novel sacroiliac joint arthrodesis system.
Donald Sachs, M.D.

Methods
• Medical charts reviewed for perioperative metrics: complications,
• pain scores (0-10 numerical rating scale) and satisfaction with surgery.
• Community based spine practice
• Diagnosed with degenerative sacroiliitis or SIJ disruption
• Failed a minimum of 6 months of nonoperative care: medication, physical therapy and injections.

<table>
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<tr>
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<tbody>
<tr>
<td>Age</td>
<td>65 (range 45-82)</td>
</tr>
<tr>
<td>Gender</td>
<td>10 F (91%), 1 M (9%)</td>
</tr>
<tr>
<td>Prior lumbar spine surgery</td>
<td>3 (27%) 2 fusion, 1 laminectomy</td>
</tr>
</tbody>
</table>
Sachs, 2012

Sachs: Pain Scores
(Rate your pain 0-10)

Average Pain Scores

Pre-op: 7.9
12+ mos: 2.3
Sacroiliac Fusion with IFuse Implant System
NCT01640353
**SIFI: Sacroiliac Joint Fusion with iFuse Implant System**

**Design**
- Prospective, Multicenter, Single-arm
- Enrollment: 172 enrolled & treated
  - 26 US clinical trial sites
- Follow-up: 1, 3, 6, 12, 18, 24 mo

**Outcome Measures**
- **Primary** (success @ 6mo)
  - VAS pain decrease ≥ 20mm
  - No device-related SAEs
  - No neurologic deficit
  - No surgical re-intervention
- **Secondary**
  - VAS SI joint pain
  - VAS back pain
  - ODI
  - QOL (SF-36 and EQ-5D)
  - Ambulatory status
  - Work status

ClinicalTrials.gov ID: NCT01640353
SIFI Prospective Multicenter: 2-yr Results

- 172 patients, 26 US sites
- Sustained clinical outcomes (VAS, ODI, QOL)
- 28% reduction in number of subjects taking opioids (baseline to 2 years)
- Radiographs show high rate (97%) of bony apposition (on at least 2 implants on both the iliac and sacral sides)

### Results

**VAS SI Joint Pain**

- 53 pt mean improvement

**ODI**

- 24 pt mean improvement

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Published in *International Journal of Spine Surgery* – April 20, 2016

Consistent Prospective Study Results
INSITE, iMIA, SIFI

Sturesson – Eur Spine J 2016 (iMIA 6mo)
Polly – Int J Spine Surg 2016 (INSITE 2yr)
Duhon – Int J Spine Surg 2016 (SIFI 2yr)
4 Studies Demonstrate Durable Results

Rudolf 2012¹ / Rudolf 2014²
50 patients out 2 years
17 of 50 pts followed to 5 years

Vanaclocha 2014³
24 patients; followed up to 4.5 years

Sachs 2016⁴
107 patients, 7 sites, 3.7yr follow-up

SI Joint Bone Bridging: 87% of patients²

Average Pain Score, VAS
0= No Pain and 10 = Worst Pain

1. Rudolf – Open Orthop J 2012. (Founder)
Systematic Review

All published cohorts of lateral approach joint-transfixing SIJ fusion
Most cohorts (85%*) were treated with iFuse Implant System

VAS SI Joint Pain

Dot area is proportional to the inverse variance of each study’s estimate

Gray line shows regression fit

*368 of 432 unique patients

Systematic Review
All published cohorts of lateral approach joint-transfixing SIJ fusion
Most cohorts (85%*) were treated with iFuse Implant System

ODI

Hollow Modular Anchorage Screw
- Al-khayer 2008 (n=9)

iFuse Implant System*
- Cummings 2013 (n=18)
- Duhon 2013 (n=32)
- Gaetani 2013 (n=12)
- Ledonio 2014 (n=17)
- Rudolf 2014 (n=17)
- Schroeder 2013 (n=6)
- Vanaclocha 2014 (n=24)
- Whang 2015 (n=102)

Gray line shows regression fit

* 368 of 432 unique patients


Dot area is proportional to the inverse variance of each study’s estimate

Months since surgery

Oswestry Disability Index score
Open vs. iFuse

iFuse Provided Better Operative Measures vs. Open

- Shorter surgery time\textsuperscript{1,2,3}
- Less estimated blood loss\textsuperscript{1,2}
- Fewer days in the hospital\textsuperscript{1,2,3}

iFuse Provided Better Clinical Outcomes vs. Open

- Better pain relief (VAS) at 12 and 24 months\textsuperscript{1}
- Better disability improvement (ODI)\textsuperscript{2,3}

2. Ledonio – *Clin Orthop Relat Res* 2014
INSITE – 12-month Results
Published ahead of print Aug 19, 2015

Randomized Controlled Trial of Minimally Invasive Sacral Iliac Joint Fusion Using Triangular Titanium Implants Vs Nonsurgical Management for Sacroiliac Joint Dysfunction: 12-Month Outcomes.

Polly, David W, MD; Cher, Daniel J, MD; Wine, Kathryn D, MPH; Whang, Peter G; Frank, Clay J, MD; Harvey, Charles F, MD; Lockstadt, Harry MD; Glaser, John A, MD; Limoni, Robert P, MD; Sembrano, Jonathan N, MD; For the INSITE Study Group

http://journals.lww.com/neurosurgery/Abstract/publishahead/Randomized_Controlled_Trial_of_Minimally_Invasive.97582.aspx

Proprietary and Confidential.
Improves more after SI joint fusion than NSM

- Probability iFuse superior to NSM >0.9999
- No crossover (9)
- 79.5% (35/44) NSM subjects crossed over after 6mo
- 54.2 point improvement @ 12mo (P < 0.001)
- P<.0001 for reduction after crossover

INSITE 12-month Results: VAS SI Joint Pain

Polly – Neurosurgery 2015
MONTHS AFTER RANDOMIZATION

NSM
SI Joint Fusion

Probability iFuse superior to NSM ≥0.9999

No crossover (9)

79.5% (35/44) NSM subjects crossed over after 6mo

P<0.0001 for reduction after crossover

Proprietary and Confidential.

INSITE 12-month Results: ODI

Improves more after SI joint fusion than NSM

Polly – Neurosurgery 2015
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>
<thead>
<tr>
<th>Revision Rate</th>
<th>Procedure Description</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.5%</td>
<td>iFuse, MIS SIJ Fusion</td>
<td>(Cher – MDER 2015)¹</td>
</tr>
<tr>
<td>10-12%</td>
<td>Lumbar Decompression</td>
<td>(Deyo – JBJS Am 2011)</td>
</tr>
<tr>
<td>12-14%</td>
<td>Lumbar Fusion</td>
<td>(Martin – Spine 2007)</td>
</tr>
</tbody>
</table>

Cumulative probability of all-cause revision after iFuse Implant System. Shaded areas represent 95% confidence intervals.

2.6% * iFuse Implant System Overall Revision Rate (August 2016)

SI-BONE corporate records

¹ Cher – Med Device Evid Res 2015
# Economics of SI Joint Treatment

## Medicare

| Non-surgical Management | 5-year total cumulative direct cost \(\approx \$5.4B\) for the Medicare population as a whole.  
3X cost for patients with prior lumbar fusion vs. w/o.¹ |
|-------------------------|--------------------------------------------------------------------------------------------------|
| MIS SI joint fusion     | $660M savings vs. NSM over patients’ lifetime.  
$3,328 savings/patient.² |

## Commercial

| Non-surgical Management | Estimated 3-year costs $1.6B per 100K lives.  
5X cost for patients with prior lumbar fusion vs. w/o.³ |
<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
<td>MIS SI joint fusion</td>
<td>Higher initial cost largely offset by decreased non-operative care over 5 years.⁴</td>
</tr>
</tbody>
</table>

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¹ Ackerman – *J Neurosurg Spine* 2014  
² Ackerman – *Clinicoecon Outcomes Res* 2013  
³ Ackerman – *Clinicoecon Outcomes Res* 2014a  
⁴ Ackerman – *Clinicoecon Outcomes Res* 2014b
### 5-year Clinical & Radiographic Outcomes

**Retrospective, single center (Dr. Leonard Rudolf)**

17 patients (15 with radiographic imaging)

<table>
<thead>
<tr>
<th></th>
<th>Clinical significant relief sustained for 5 years:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>8.3</td>
</tr>
<tr>
<td>12mo</td>
<td>3.4 (-5.1 chg)</td>
</tr>
<tr>
<td>60mo</td>
<td>2.4 (-5.9 chg)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Mean ODI at 5 years</th>
<th>21.5 (moderate disability)</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Qualitative x-ray and CT</th>
<th>Increased bone density immediately adjacent to all walls of all implants</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>87% (13/15) of patients had intra-articular osseous bridging</td>
</tr>
<tr>
<td></td>
<td>No evidence of implant loosening or migration</td>
</tr>
</tbody>
</table>

| Safety                   | No long-term complications                                               |

**Oswestry Disability Index (ODI) Score Interpretation** [Fairbank 2000]

- 0-20 = minimal disability
- 21-40 = moderate
- 41-60 = severe
- 61-80 = crippled
- 81-100 = bed-bound (or patients are exaggerating their symptoms)

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Figure 6: (A) Sagittal CT scan of the iliac portion of the joint shows a sclerotic margin surrounding the edges of the superior implant. Areas of “spot-welds” (arrows) noted between the sclerotic margin and implant walls is suggestive of biological fixation. Artifact is seen at the corners of the implant (triangle). (B) Sacral side shows increased bone density adjacent to the implant walls.
Thank you!
Pin Placement

INITIAL PIN PLACEMENT

Lateral

Inlet

Outlet

FINAL PIN PLACEMENT

Lateral

Inlet

Outlet

Confidential & Proprietary
iFuse Implant System

Blunt Dissector

Soft Tissue Protector

*click*

Pin Depth = Implant Length

55 mm should be used in this example.

70 mm should be used in this example.

Confidential & Proprietary
Clinical Results
3 Imaging Views are used for the technique.

- Lateral View
- Inlet View
- Outlet View
Insert Pin

Drill
Broach

Implant

Tapered End
Repeat Steps for Subsequent Implants
### Published Literature Supporting Medical Necessity

<table>
<thead>
<tr>
<th>Author</th>
<th># of Patients</th>
<th>Publication Date</th>
<th>Journal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rudolf</td>
<td>50</td>
<td>11/2012</td>
<td>Open Orthopaedics J</td>
</tr>
<tr>
<td>Sachs</td>
<td>11</td>
<td>12/2012</td>
<td>Ann Surg Innov &amp; Res</td>
</tr>
<tr>
<td>Rudolf</td>
<td>40</td>
<td>05/2013</td>
<td>Open Orthopaedics J</td>
</tr>
<tr>
<td>Miller</td>
<td>5,319</td>
<td>05/2013</td>
<td>Medical Devices: Evidence and Research</td>
</tr>
<tr>
<td>Sachs</td>
<td>40</td>
<td>08/2013</td>
<td>Advances in Orthopedics</td>
</tr>
<tr>
<td>Cummings</td>
<td>18</td>
<td>09/2013</td>
<td>Ann Surg Innov &amp; Res</td>
</tr>
<tr>
<td>Gaetani</td>
<td>10</td>
<td>12/2013</td>
<td>J Neurosurgical Sciences</td>
</tr>
<tr>
<td>Duhon</td>
<td>94</td>
<td>12/2013</td>
<td>Medical Devices: Evidence and Research</td>
</tr>
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<td>6</td>
<td>12/2013</td>
<td>Hosp Special Surg J</td>
</tr>
<tr>
<td>Ledonio</td>
<td>44</td>
<td>02/2014</td>
<td>Clin Orthop Relat Res</td>
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<td>39</td>
<td>06/2014</td>
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<td>Sachs</td>
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Only SI-BONE has this level of supporting literature related to the SI joint and MIS SI joint fusion.
Overlapping Pain Diagrams


**History**

**Pain Diagram** (19)

- 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

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Injection Assessment

- **Patient pain diary**
- **Significant positive clinical response**
  - 50-75% VAS reduction indicates positive diagnosis of SI joint as pain generator
  - *Obtain copy of arthrogram to ensure accuracy*
- **Equivocal or no relief**
  - < 50% VAS reduction indicates a non-significant clinical response
  - May have SIJ pain, but consider other pain sources
Surgical Procedure

- Pin
- Drill
- Broach
- Implant
The iFuse Implant System is intended for sacroiliac joint fusion for conditions including sacroiliac joint dysfunction that is a direct result of sacroiliac joint disruptions and degenerative sacroiliitis.

- Designed specifically to **stabilize and fuse** the heavily loaded SI joint
- **Rigid titanium constructs** provide immediate stability
- **Triangular implant profile** minimizes rotation and an interference fit minimizes micro-motion
- **Porous titanium plasma spray (TPS) coated implants**
- **Implant is 3 times stronger** under shear and bending loads compared to 8.0mm screws (data on file)
- **13,000 procedures performed Worldwide** (October 2014)
- **Minimally invasive**: delivered to the SI joint using a cannulated delivery system designed to protect soft tissues
iFuse - A Simple Procedure

- Incision
- Pin
- Drill
- Broach
- Implant
Offers post-op SI joint stability

Straight forward, minimally invasive (MIS) surgical approach; does not require any preparation of the joint or bone graft

Designed specifically to stabilize the heavily loaded SI joint

Implant profile and design minimizes rotation and micromotion

The iFuse System is intended for sacroiliac joint fusion for conditions including sacroiliac joint disruptions and degenerative sacroiliitis. As with all surgical procedures and permanent implants, there are risks and considerations associated with surgery and use of the iFuse Implant. Please review the iFuse Instructions For Use for a complete discussion of contraindications, warnings, precautions, and risks.
Patient Set-Up

- Patient placed on a flat Jackson Table
- Towel rolls placed transversely under chest and waist
- Spine neutral and hip neutral positioning
- Pillows under feet to relax legs
Intraoperative Imaging

Three imaging views are used for safe placement of instruments and Implants:

- Lateral View
- Inlet View
- Outlet View
iFuse Implant System

Drilling (Optional)

Drill Insertion

Soft Tissue Protector Alignment

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iFuse Implant System

Implant Insertion

Implant Advancement

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### iFuse Implant System

<table>
<thead>
<tr>
<th>Inlet Oblique View</th>
<th>Outlet Oblique View</th>
<th>Implant Depth</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image1" alt="Inlet Oblique View" /></td>
<td><img src="image2" alt="Outlet Oblique View" /></td>
<td><img src="image3" alt="Implant Depth" /></td>
</tr>
</tbody>
</table>

- **Lateral cortical wall**

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iFuse Implant System

Repeat Steps

Final Implant Placement
Implant Position
Compared to the lumbar spine, SI joints can withstand a medially directed force 6 times greater but only half the torsion and 1/20th of the axial compression load.

The long-term success rate for SI joint fusion appears to be in the range of 70%.

The SI joint is a real yet underappreciated pain generator in an estimated 15 - 25% of patients with axial LBP.
## SIFI 24-month Results

### Safety Profile

<table>
<thead>
<tr>
<th>Device-related</th>
<th>7 events</th>
</tr>
</thead>
<tbody>
<tr>
<td>3 Neuropathy related to malposition</td>
<td></td>
</tr>
<tr>
<td>2 SI joint or buttock pain</td>
<td></td>
</tr>
<tr>
<td>1 SI joint pain after fall assoc. with inadequate device placement</td>
<td></td>
</tr>
<tr>
<td>1 Hip pain related to periosteal bone growth around implant</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Procedure-related</th>
<th>26 events</th>
</tr>
</thead>
<tbody>
<tr>
<td>Buttock pain (2), foot pain related to anesthesia (1), Ifuse impingement (3), nausea/vomiting, SI joint pain (5), SI joint pain due to inadequate stabilization (3), urinary retention (1), vascular injury (1), wound drainage/irritation/infection (6), wound numbness (1)</td>
<td></td>
</tr>
</tbody>
</table>

### Revision Surgery | 8 cases (4.7%) |
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>2 – immediate postop new onset leg pain due to implant malposition. Resolved with slight repositioning.</td>
<td></td>
</tr>
<tr>
<td>4 – minimal pain improvement, CT scan showed suboptimal implant placement (lower implants not sufficiently in the sacrum). Resolved with additional implants.</td>
<td></td>
</tr>
<tr>
<td>1 – bilateral SIJ fusion, recurrent pain 6mo later; resolved with open SIJ fusion and additional implant.</td>
<td></td>
</tr>
<tr>
<td>1 – subject had L4-S1 fusion 13mo post SIJ fusion, recurrent pain showed S1 screw touching implant. Resolved with additional non-iFuse device put across SI joint.</td>
<td></td>
</tr>
</tbody>
</table>
### Quality of Life (QOL) via Short Form 36 (SF-36)

<table>
<thead>
<tr>
<th></th>
<th>Baseline</th>
<th>12mo</th>
<th>24mo</th>
</tr>
</thead>
<tbody>
<tr>
<td>PCS</td>
<td>31.7</td>
<td>40.5</td>
<td>40.7</td>
</tr>
<tr>
<td>MCS</td>
<td>38.5</td>
<td>48.2</td>
<td>49.0</td>
</tr>
</tbody>
</table>

*p < 0.0001 for both PCS and MCS*

### Effectiveness Outcomes

**Patient Satisfaction**
(somewhat or very satisfied)

- 93.8%

**Opioid Use Reduction**
(% subjects using opioids, baseline to 2 year)

- 28.2% ↓

**PCS = Physical Component Summary**
**MCS = Mental Component Summary**

Duhon – *Global Spine J* 2015
Rapid and Sustained Pain Relief – VAS SI Joint Pain

Complete References in Bibliography

* Measured lower back pain
Reduction in Disability – Oswestry Disability Index

Starting baseline value

Last follow-up value after fusion

p-values comparing baseline to last follow-up

† MCID: Minimum Clinically Important Difference ≥12.8 point drop [Copay 2008]

‡ SCB: Substantial Clinical Benefit ≥18.8 point drop or final score <31.3 [Glassman 2008]

Bed-bound

Crippled

Severe Disability

Moderate Disability

Minimal Disability

Cummings 2013
Mean 10 mo (n=18)

Gaetani 2013
Mean 10 mo (n=10)

Schroeder 2013
Mean 10 mo (n=8)

Ledonio 2014(a)
Median 15 mo (n=22)

Ledonio 2014(b)
Median 15 mo (n=17)

Vanaclocha 2014
54 mo (n=24)

Duhaen 2016
24 mo (n=172)

Stressson 2016
RCT, 6 mo (n=52)

Polly 2016
RCT, 24 mo (n=102)

Complete References in Bibliography
## Improvement in Quality of Life

<table>
<thead>
<tr>
<th>Measurement</th>
<th>Improvement Baseline to Follow-up</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean</td>
<td>Percent</td>
</tr>
<tr>
<td><strong>Polly 2016</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>RCT, 24 mo follow-up (n=102)</td>
<td>SF-36 PCS</td>
<td>+11.2</td>
</tr>
<tr>
<td></td>
<td>SF-36 MCS</td>
<td>+8.2</td>
</tr>
<tr>
<td></td>
<td>EQ-5D TTO</td>
<td>+0.28</td>
</tr>
<tr>
<td><strong>Sturesson 2016</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>RCT, 6 mo follow-up (n=52)</td>
<td>EQ-5D TTO</td>
<td>+0.37</td>
</tr>
<tr>
<td><strong>Duhon 2016</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prospective, 24 mo follow-up (n=172)</td>
<td>SF-36 PCS</td>
<td>+8.9</td>
</tr>
<tr>
<td></td>
<td>SF-36 MCS</td>
<td>+10.1</td>
</tr>
<tr>
<td></td>
<td>EQ-5D TTO</td>
<td>+0.27</td>
</tr>
<tr>
<td><strong>Gaetani 2013</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10 mo mean follow-up (n=10)</td>
<td>Roland-Morris Disability</td>
<td>-14.6</td>
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<tr>
<td><strong>Cummings 2013</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>12 mo follow-up (n=18)</td>
<td>SF-12 PCS</td>
<td>+11.2</td>
</tr>
<tr>
<td></td>
<td>SF-12 MCS</td>
<td>+20.4</td>
</tr>
</tbody>
</table>

- Statistically significant improvement
- Consistent improvement across multiple quality of life measures

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Complete References in Bibliography

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High Patient Satisfaction

Patient satisfaction
91% Average

Complete References in Bibliography
It is common for pain from the SI joint to mimic discogenic or radicular low back pain.

Many patients go on to receive lumbar fusion instead of SI joint fusion, so SI joint disease should be strongly considered in differential diagnosis of low back pain.

Estimation of prevalence of SI joint dysfunction, using fluoroscopic infiltration as the basis of diagnosis, ranges from 13 - 30%. The prevalence is even higher after failed back surgery, reaching about 63%.