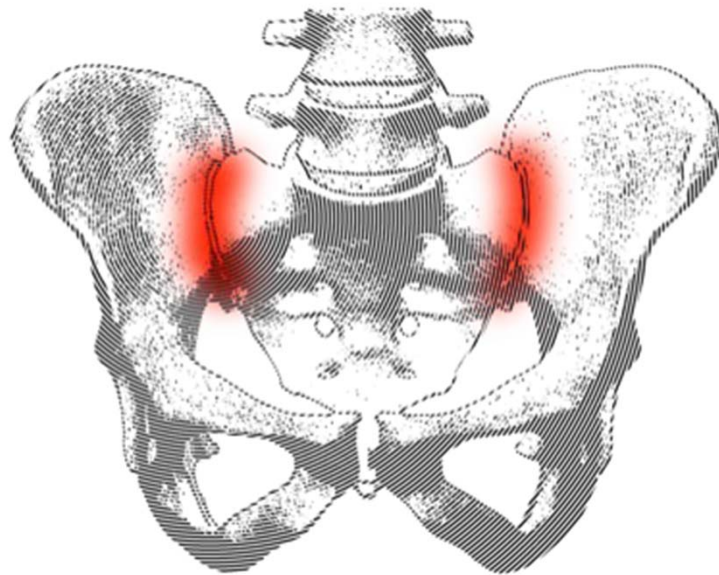


Diagnosis and Treatment of the Sacroiliac Joint



Clay J. Frank MD



Medical School:

Medical College of Wisconsin

Residency:

Orthopedic Surgery

Nebraska University Health Foundation

Fellowship:

Orthopedic Spine Surgery,

Carolinas Medical Center, Charlotte, NC

Practice:

Injured Reserve!

Speaker Disclosures

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?**

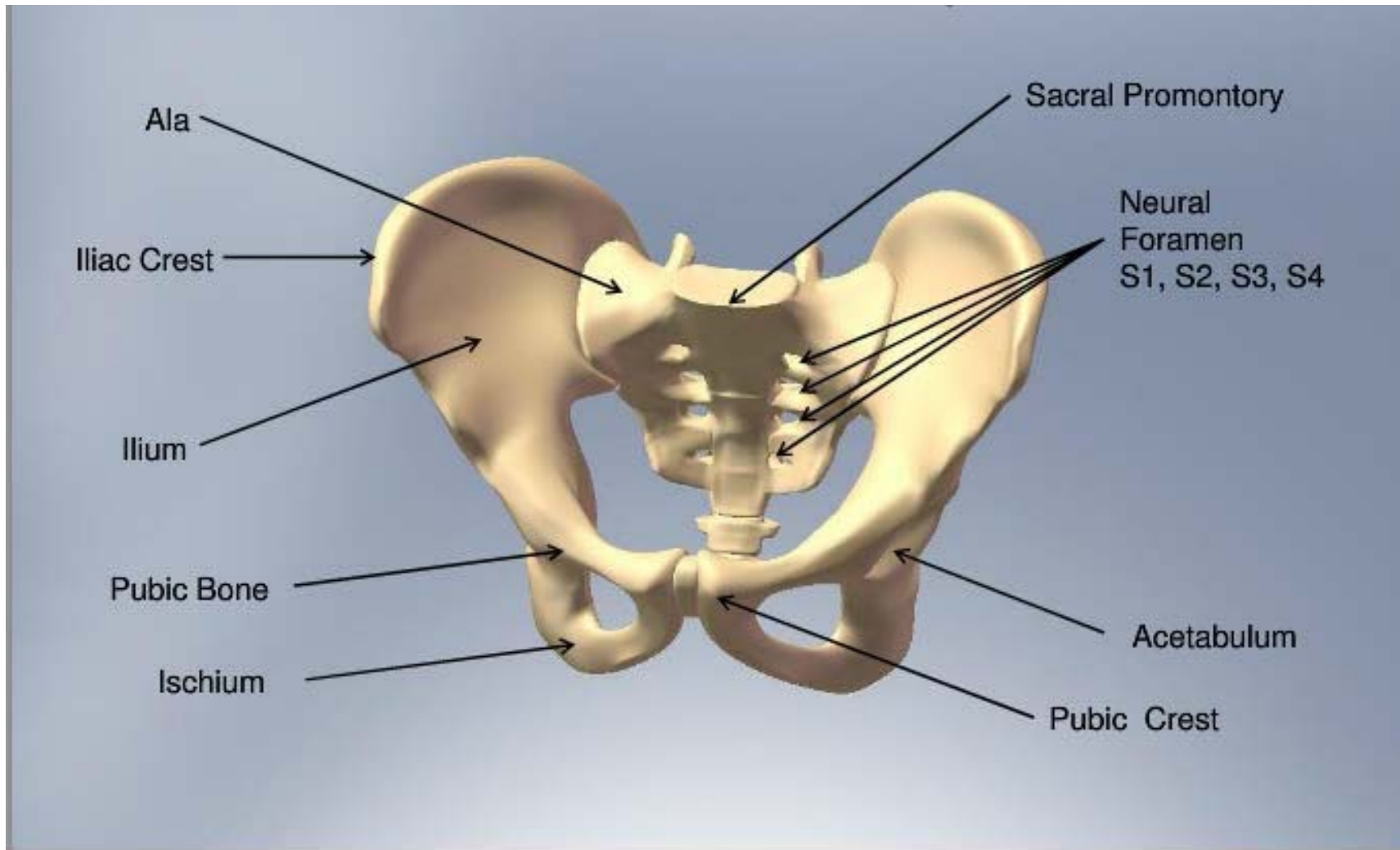
“Right Here Doc”



Fortin & Falco – Am Journal of Ortho 1997

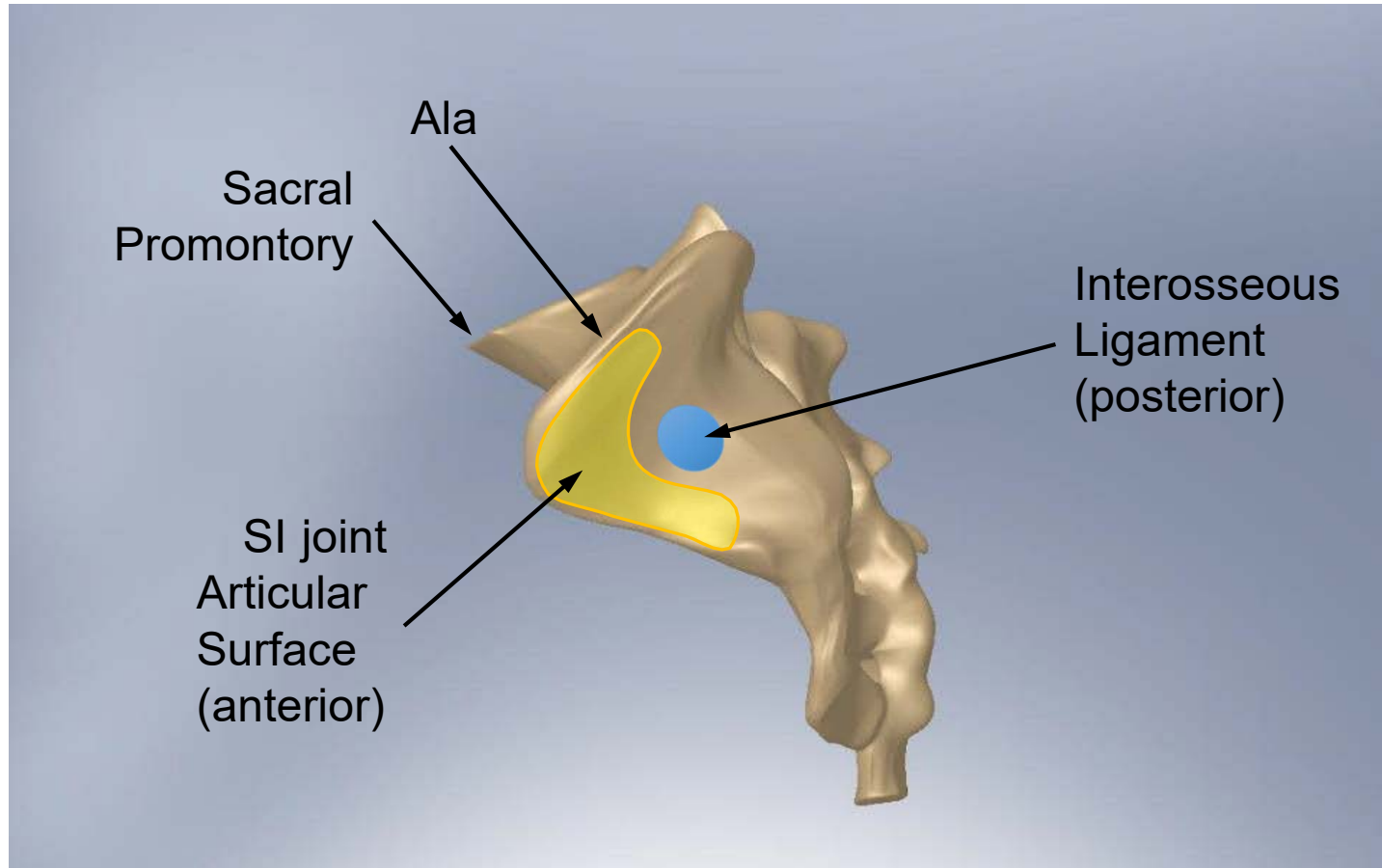
Anatomy

Sacroiliac Joint



Anatomy

Lateral Sacrum



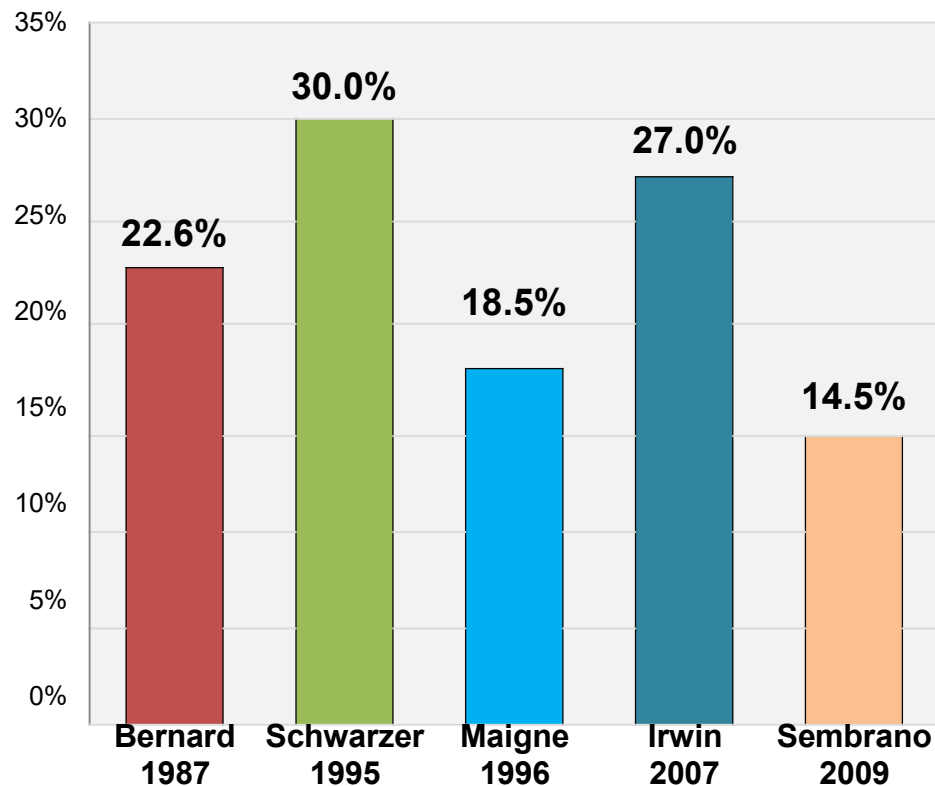
Prevalence of SI Joint Pain



Prevalence of SI Joint Pain

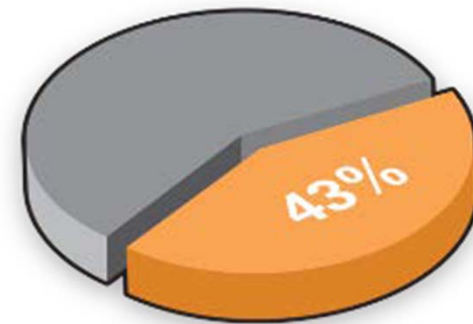
15-30%

Component of chronic LBP



32-43%

Symptomatic Post-Lumbar Fusion



DePalma – Pain Med 2011

- 32% Katz 2003
- 35% Maigne 2005
- 43% DePalma 2011
- 40% Liliang 2011

Prevalence of Work-Related SIJ Patients

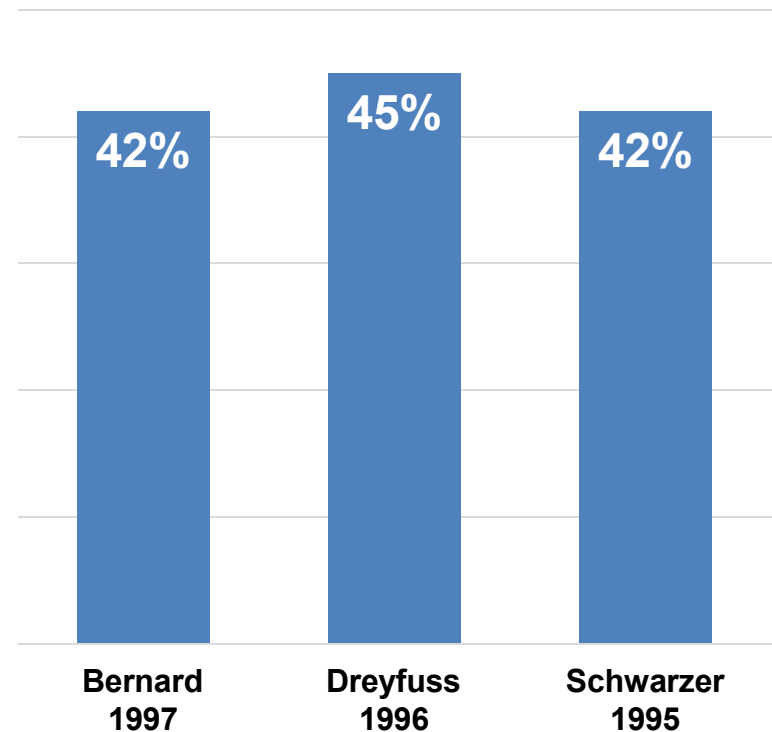
42% Bernard 1997

Compensable Injury = Worker's Comp

45% Dreyfuss 1996

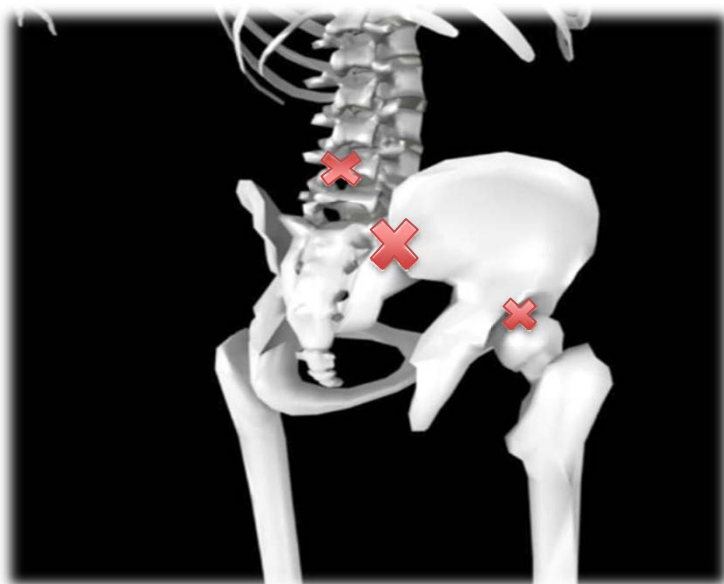
38 of 85 patients

42% Schwarzer 1995



1. Bernard TN Jr, Cassidy JD. , Frymoyer JW, ed. Lippincott-Raven Publishers, Philadelphia, 1997.
2. Dreyfuss P, et al. Spine. 1996.
3. Schwarzer AC, et al. Spine.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

Ha et al. 2008

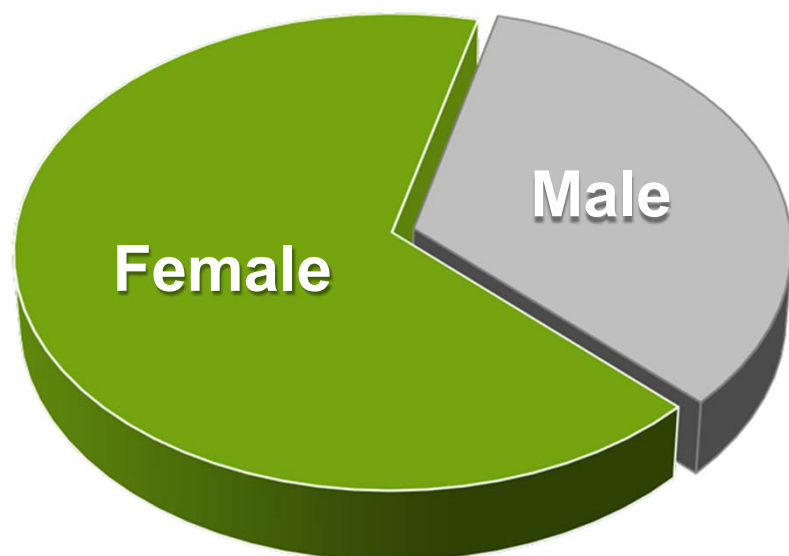
Lumbar fusion leads to increases in angular motion and joint stress at the SI joint

Ivanov et al. 2009

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*



* Based on multiple prevalence and treatment studies:
Schwarzer 1995, Irwin 2007, Sembrano 2009, Katz 2003,
Maigne 2005, DePalma 2011, Liliang 2011, Ha 2008,
Rudolf 2012, Graham Smith 2013, Ledonio 2014, Polly 2016,
Sturesson 2016, Duhon 2016, Bornemann 2016, Spain 2017
(1824 total patients, 1204 female = 66%)

Pregnancy-related Pelvic Girdle Pain (PPGP)

45% of pregnant women have lower back and/or pelvic pain¹

25% of pregnant women report severe pain¹

5% of ALL pregnant women had pain 3 years later²



1. Wu – Eur Spine J 2004
2. Norén – Eur Spine J 2002

SI-BONE®

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 Fortin Finger

Positive Provocative Tests
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

HISTORY

When did the pain start?

- 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

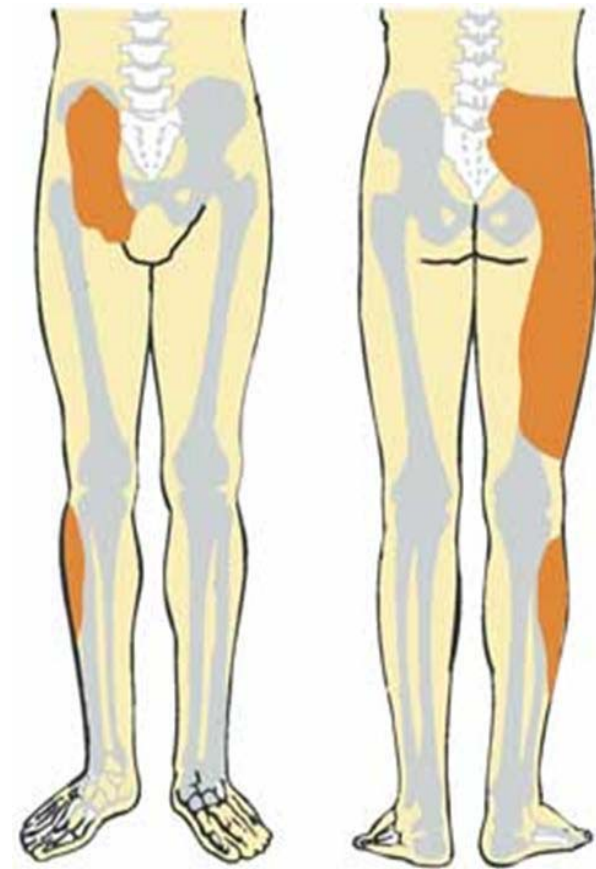
COMPLAINTS

- 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

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



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

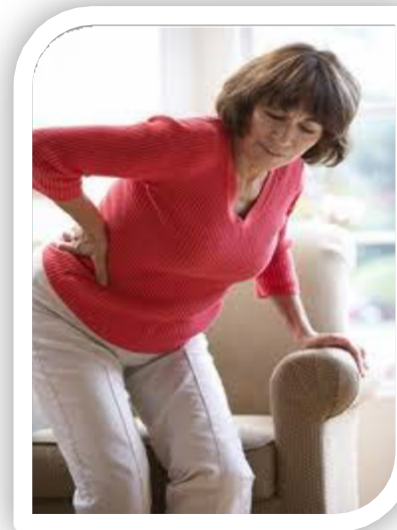
Janda – Aust J Physiotherapy 1983

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**



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



SI Joint: Provocative Tests

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**

	Laslett ^{1,2}	Szadek ³
	3 or more positive tests	
Sensitivity	91%	85%
Specificity	78%	76%

* Most sensitive of tests

** PPV = *positive predictive value*

1. Laslett – *Man Ther* 2005

2. Laslett – *J Man Manip Ther* 2008

3. Szadek – *J Pain* 2009

SI Joint Provocative Tests

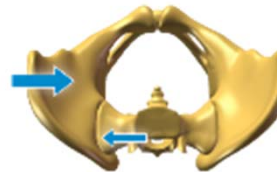
Distraction



①



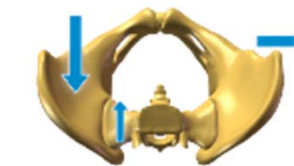
Compression



④



Thigh Thrust



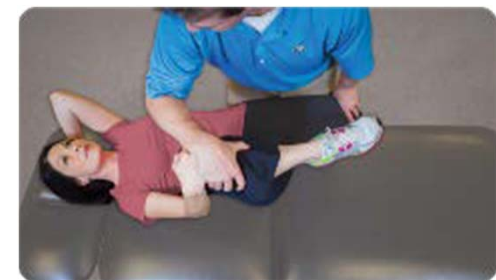
②



Gaenslen



⑤



FABER



③



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



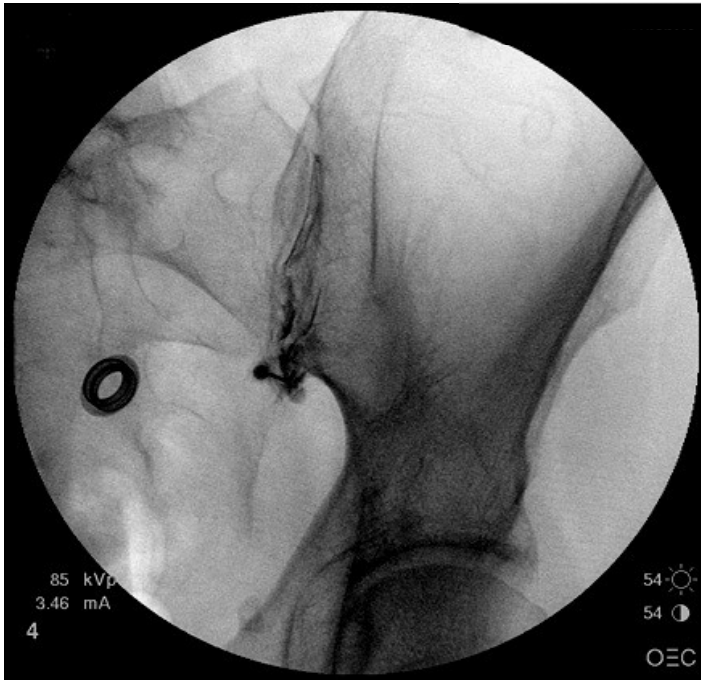
Positive
Fortin Finger Test
and
Physical Exam
(Lumbar Spine,
SI Joint, and Hip)



Positive
Provocation
Testing

What's the Reference Standard for Diagnosis?

Injection Under Fluoroscopy



1. Lorio – IJSS 2016 (ISASS Policy 2016 Update - Minimally Invasive Sacroiliac Joint Fusion)
2. Bono, et al. NASS Coverage Policy Recommendations: Percutaneous Sacroiliac Joint Fusion. June 9, 2015.

* Check payor policy for positive test criteria

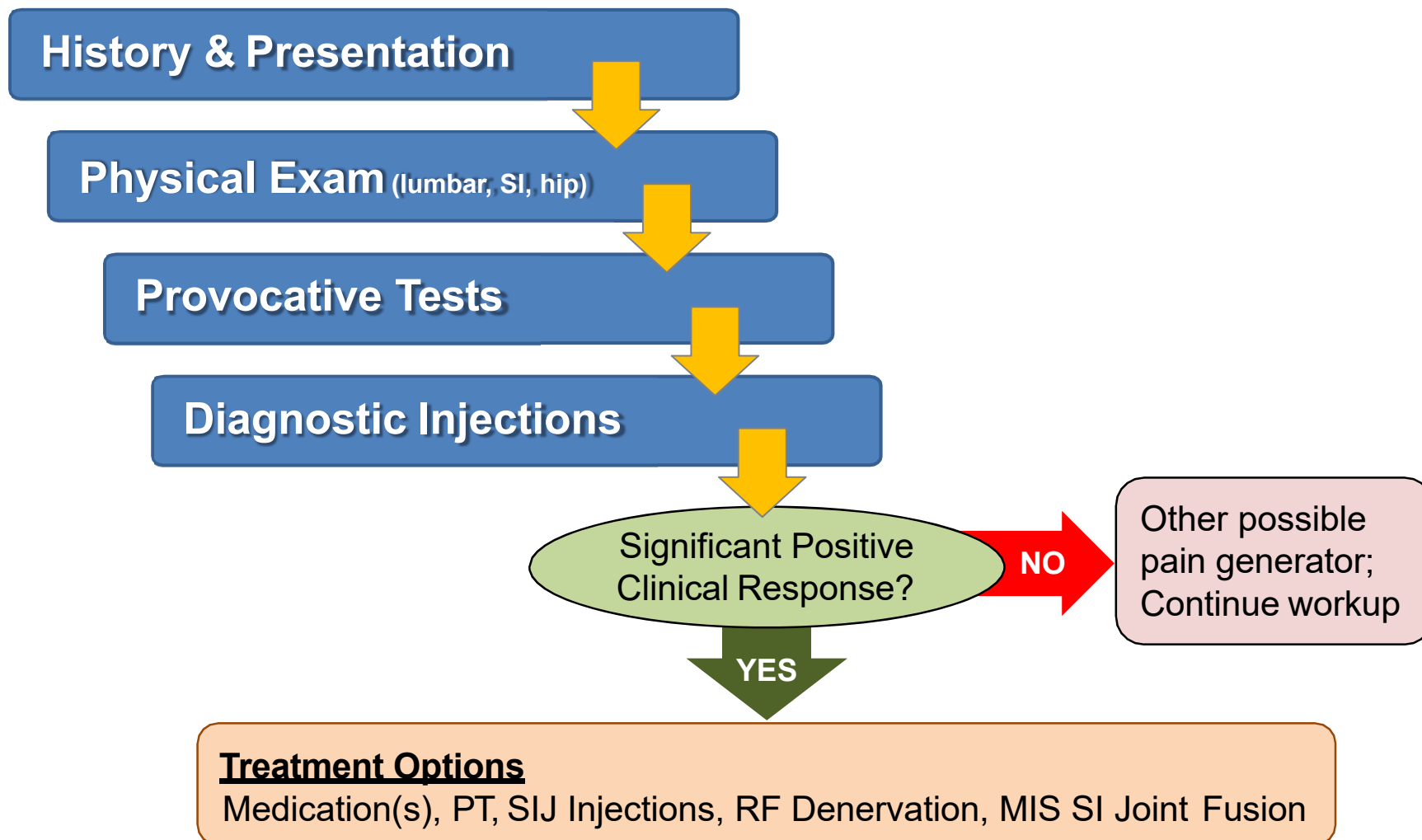
Diagnostic Injection

- Confirm with contrast and imaging
- Low volume, local anesthetic
- Pain Reduction for positive test*
 - ≥ 75% require per NASS Recommendations²
 - ≥ 50% require per ISASS Guidelines¹
 - < 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

Diagnostic Algorithm for SI Joint Pain



Non-surgical Treatment Options

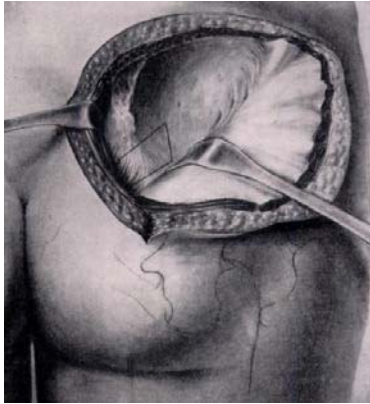
Symptom Management

- **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)

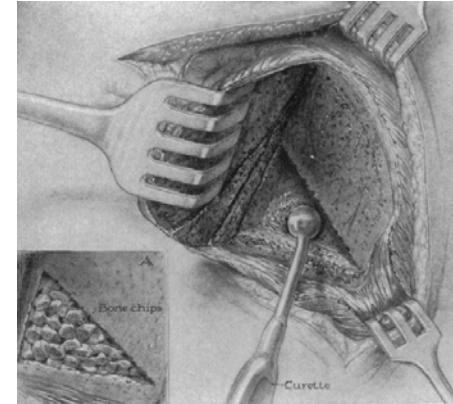
Treatment Options: Surgical



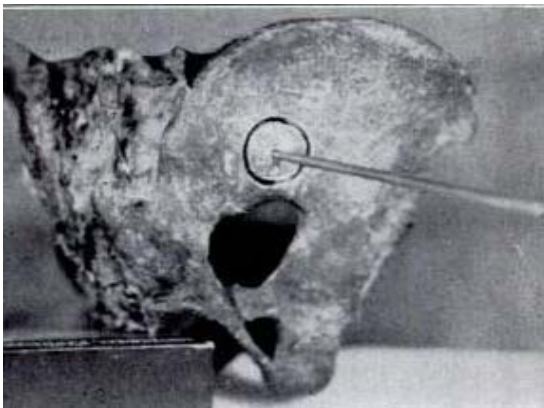
Smith-Petersen 1926



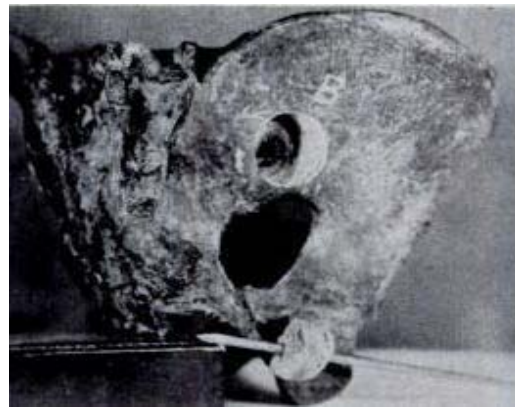
Campbell 1927



Gaenslen 1927



Bloom 1937

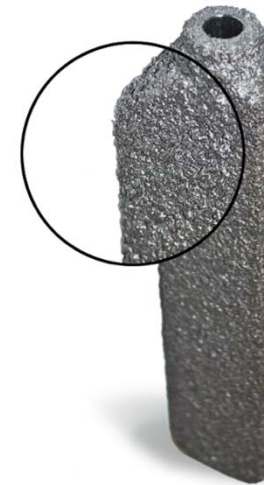


iFuse 2008

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)*

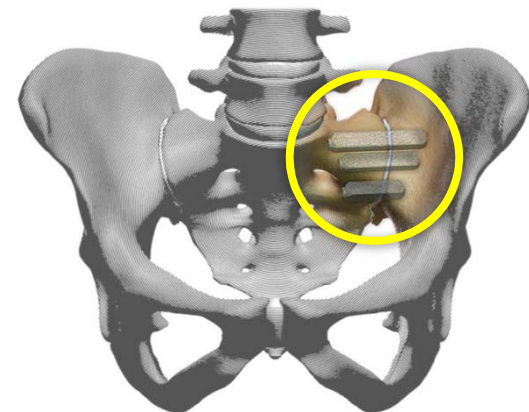


- **Strength of Experience**

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



* MacBarb G, et al. Int J Spine Surg. 2017;11;116-28.

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

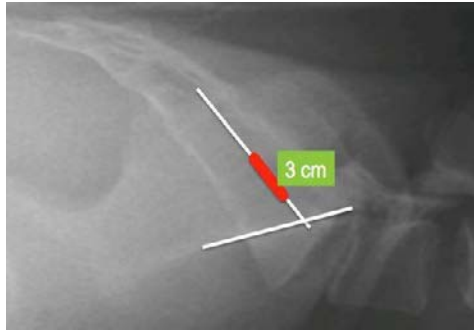
- Better pain relief (VAS) at 12 and 24 months¹
- Better disability improvement (ODI)^{2,3}

1. Graham Smith – *Ann Surg Innov Res* 2013

2. Ledonio – *Clin Orthop Relat Res* 2014

3. Ledonio – *Med Devices (Auckl)* 2014

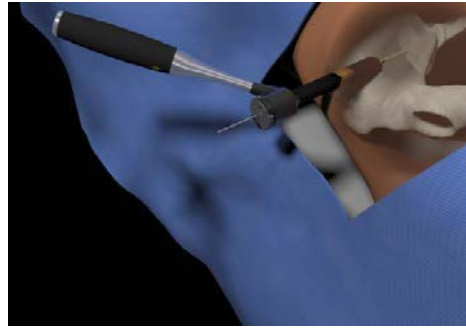
iFuse Procedure Overview



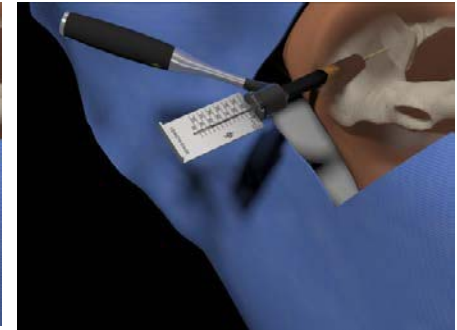
Incision
(~3 cm)



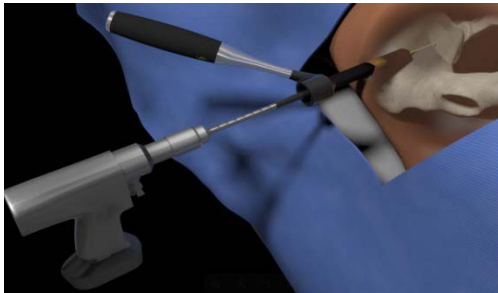
Pin



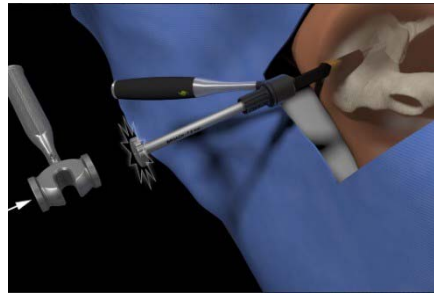
Soft Tissue
Protector



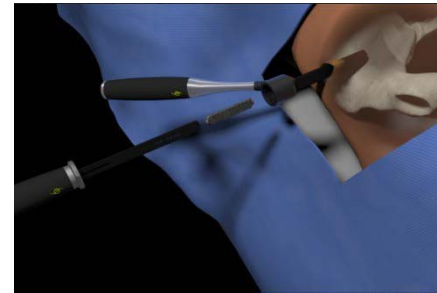
Measure



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

Clinical Evidence



Prospective Clinical Studies Overview



NCT01741025

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

6mo pub

1yr pub

The logo for the LOIS study, featuring the letters 'LOIS' in a bold, green, sans-serif font with a stylized green swoosh underneath.

LOIS

NCT02270203

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)

Completed



NCT01681004

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

Completed



NCT01640353

SIFI: Sacroiliac Joint Fusion with iFuse Implant System

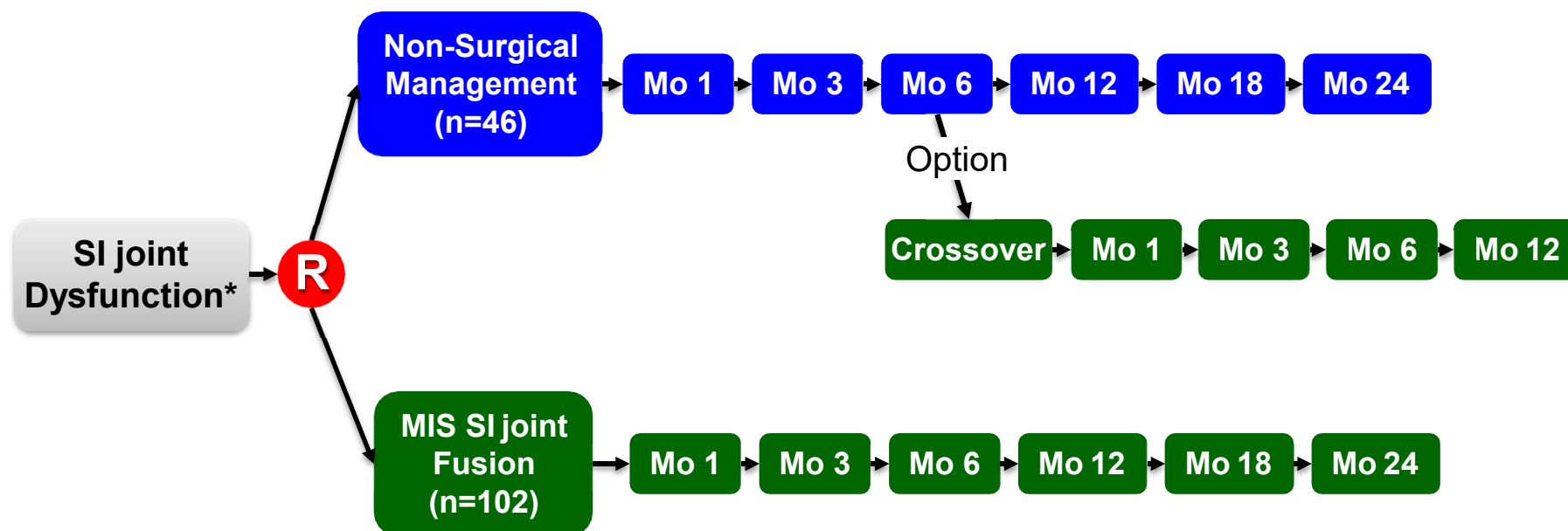
Multicenter, Prospective, Single-arm
172 patients enrolled & treated
26 sites, 24mo follow-up

First prospective study with iFuse Implant System

2yr pub

SI-BONE®

INSITE: Study Design

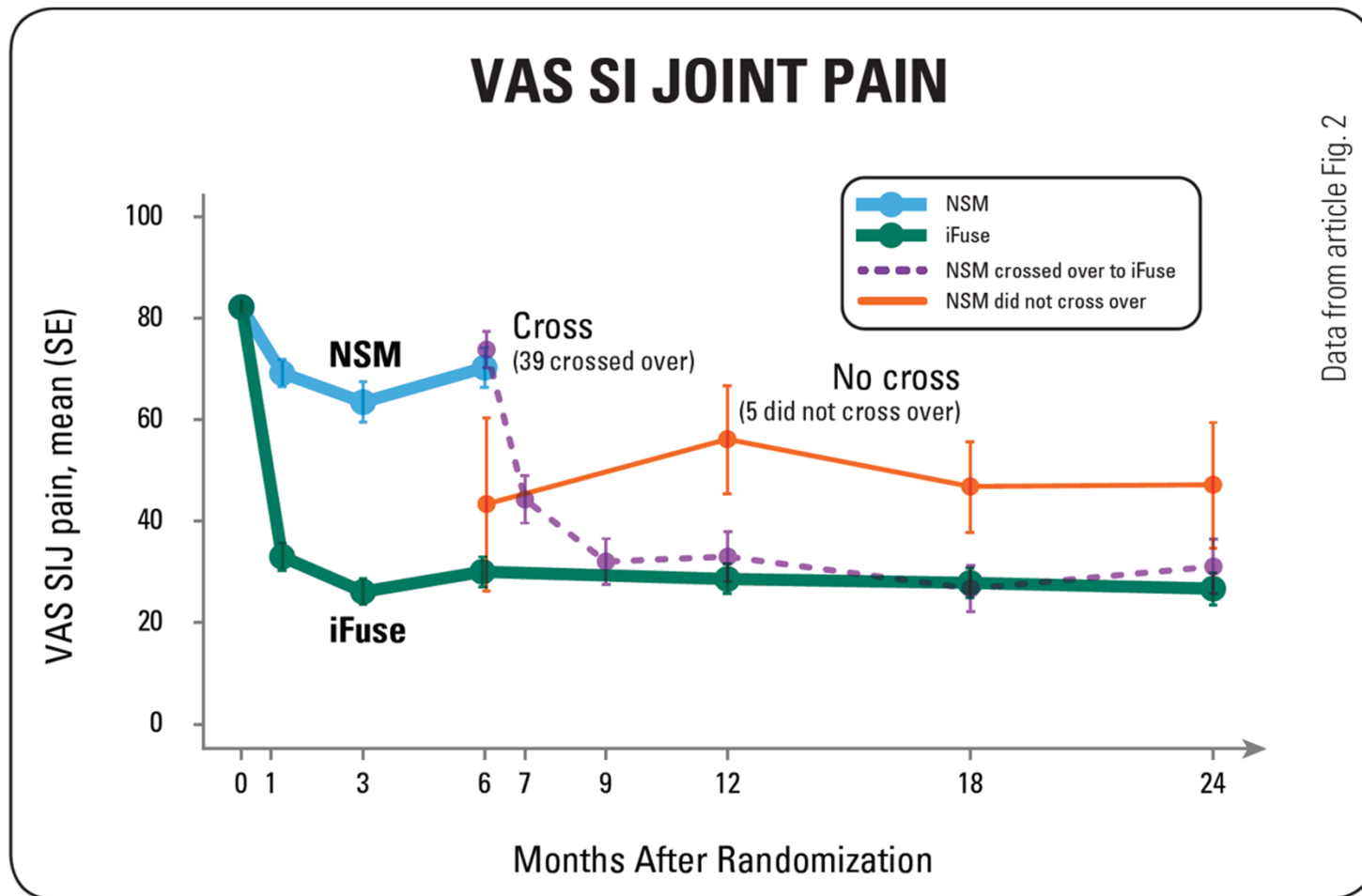


R = Randomization, 2:1 fashion to either MIS SI Joint Fusion or Non-surgical Management

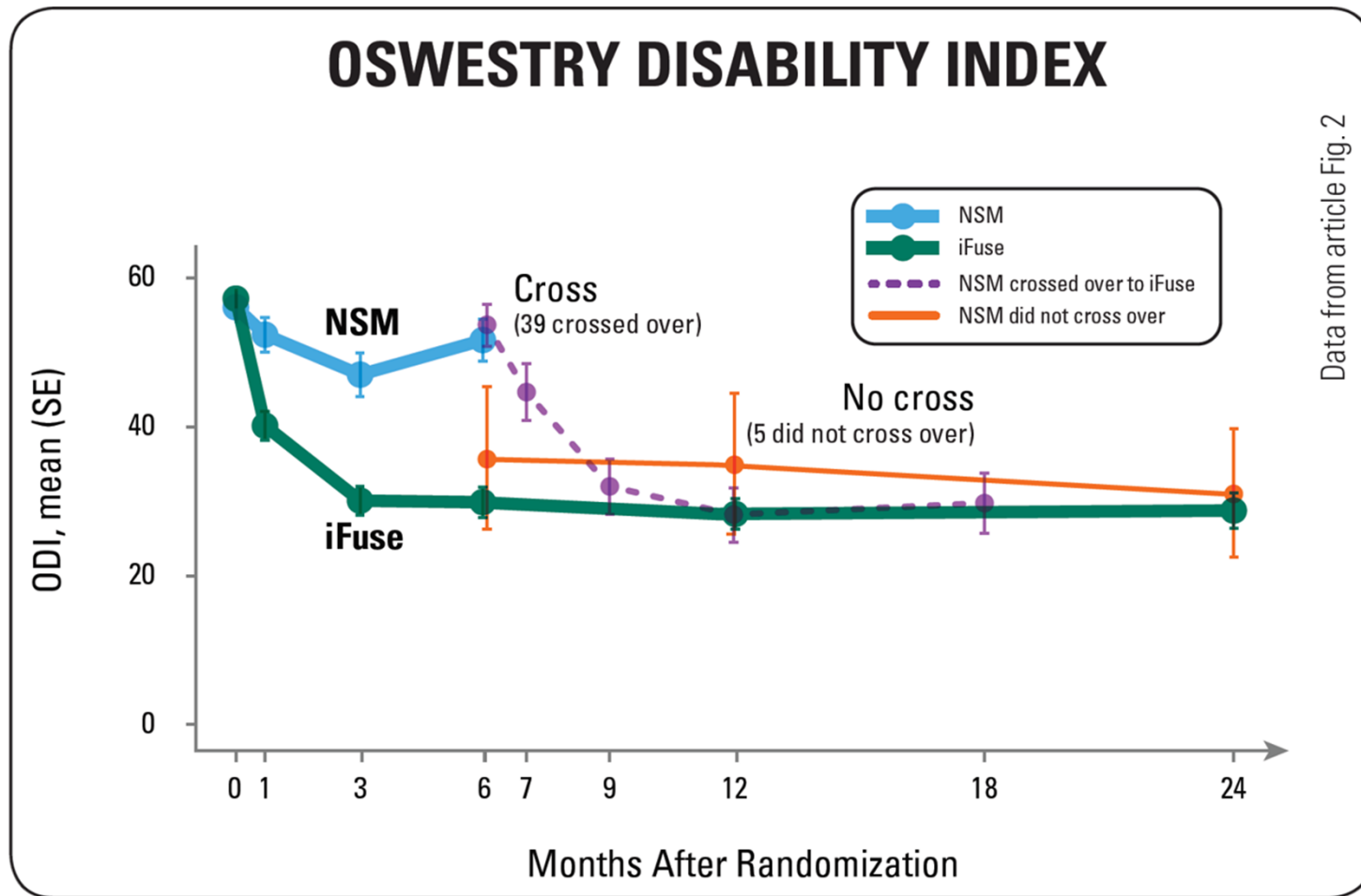
* SI joint dysfunction due to sacroiliac joint disruption and degenerative sacroiliitis

INSITE 2-year Results

Improves more after SI joint fusion than NSM



INSITE 2-year Results: Improves more after SI joint fusion than NSM



INSITE 2-year Results

Safety Profile

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

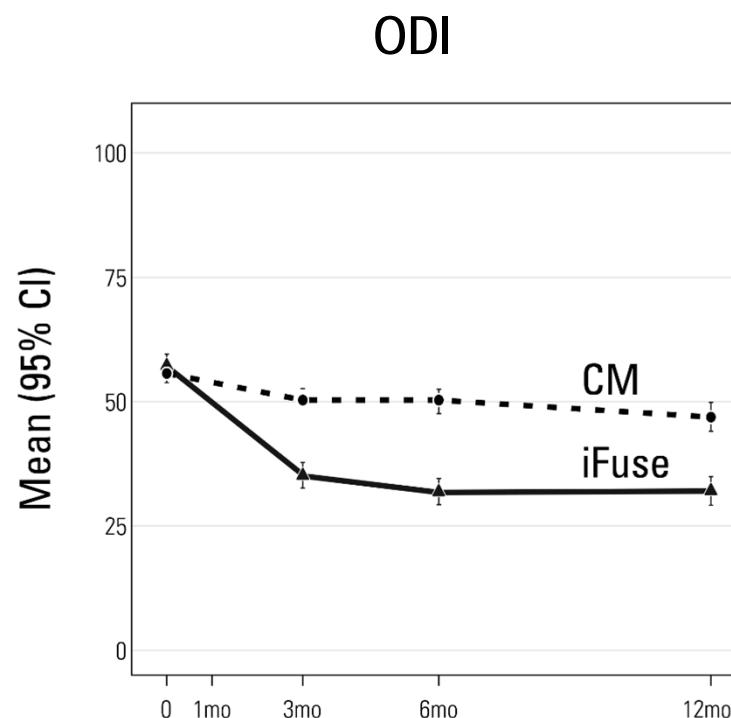
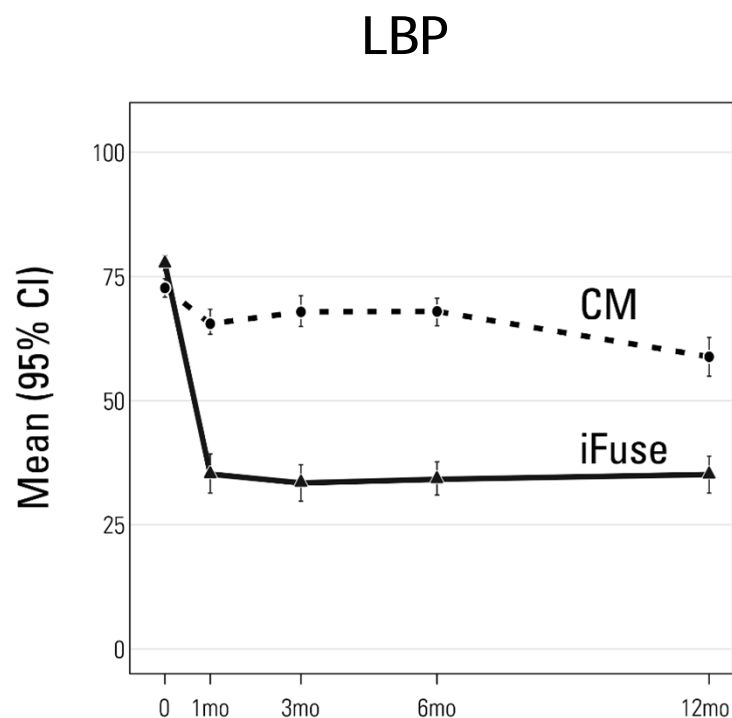
30% fewer iFuse treated patients taking opioids (baseline to 2 yr)

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

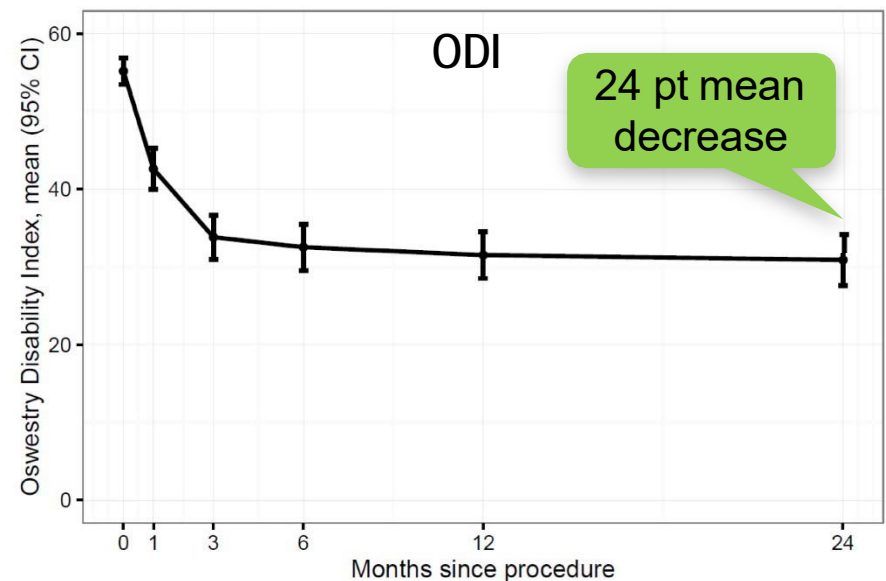
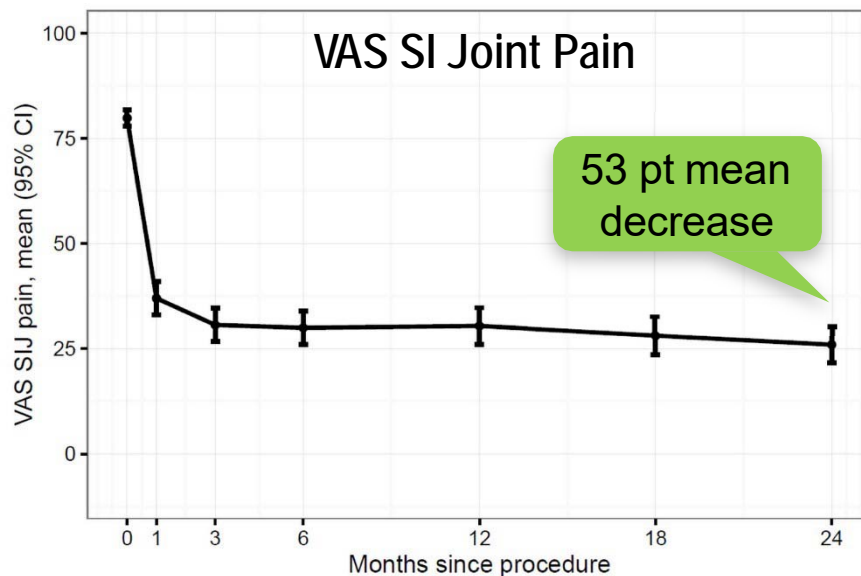


Mean change from baseline to 1 year	VAS LBP	ODI
iFuse	- 42	- 26
CM	- 14	- 8

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)



INSITE, iMIA, SIFI

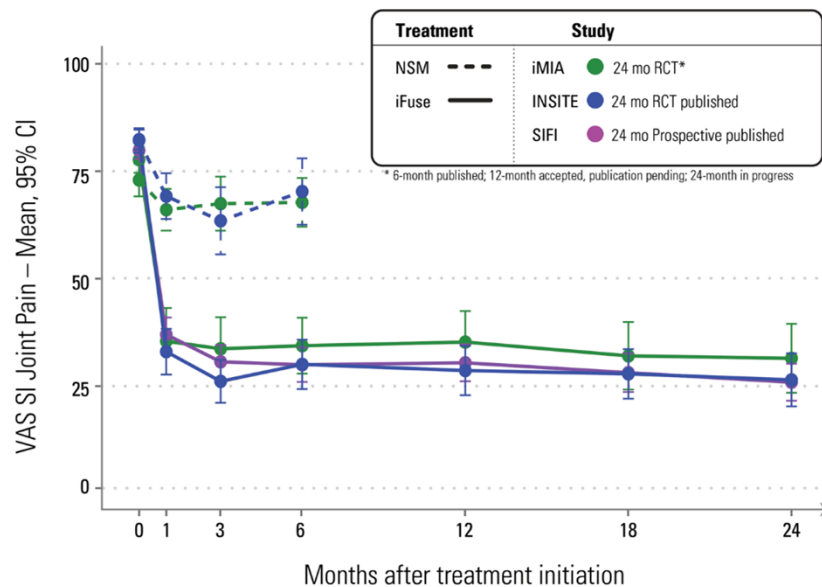
Consistent Prospective Study Results



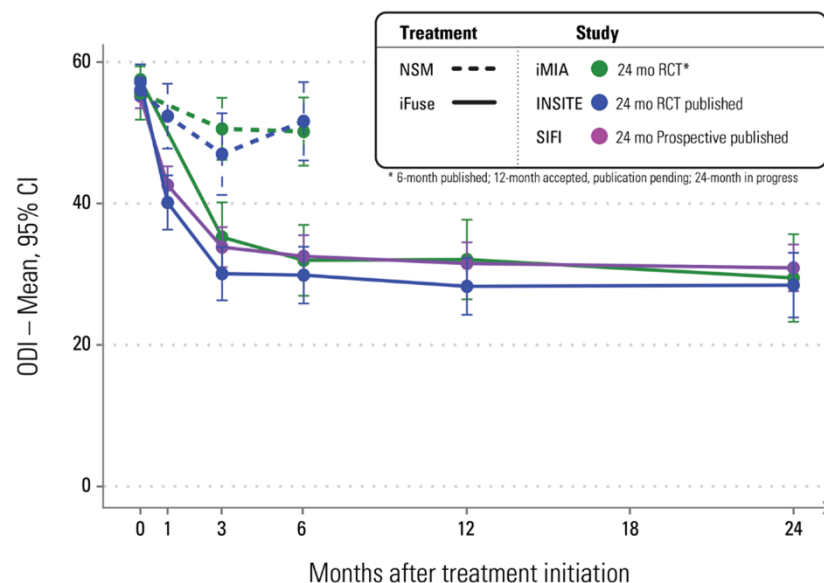
Pooled Analysis of INSITE, iMIA & SIFI

[Published ahead-of-print in SPINE – 2017 March 27](#)

VAS SI Joint Pain



Oswestry Disability Index



Graphs using data from:

iMIA 24mo data as of August 17, 2017 (publication in progress)

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

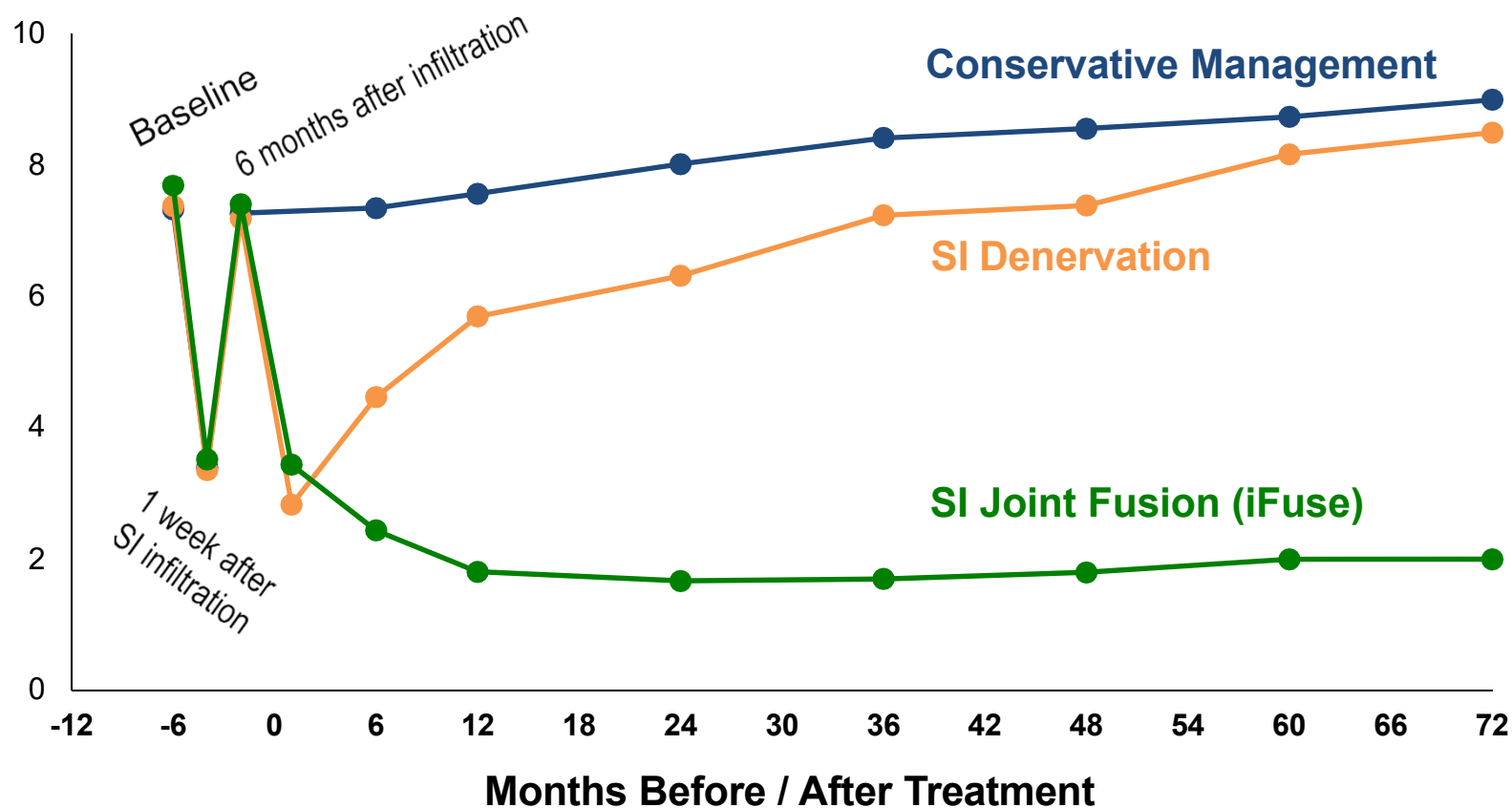
Duhon – *Int J Spine Surg* 2016 (SIFI 2yr)

CM, RF, SI Joint Fusion (iFuse) 6-Year Comparative Cohort Study

NEUROSURGERY
THE REGISTER OF THE NEUROSURGICAL MEME

Published: 2017 April 20

VAS SI Joint Pain



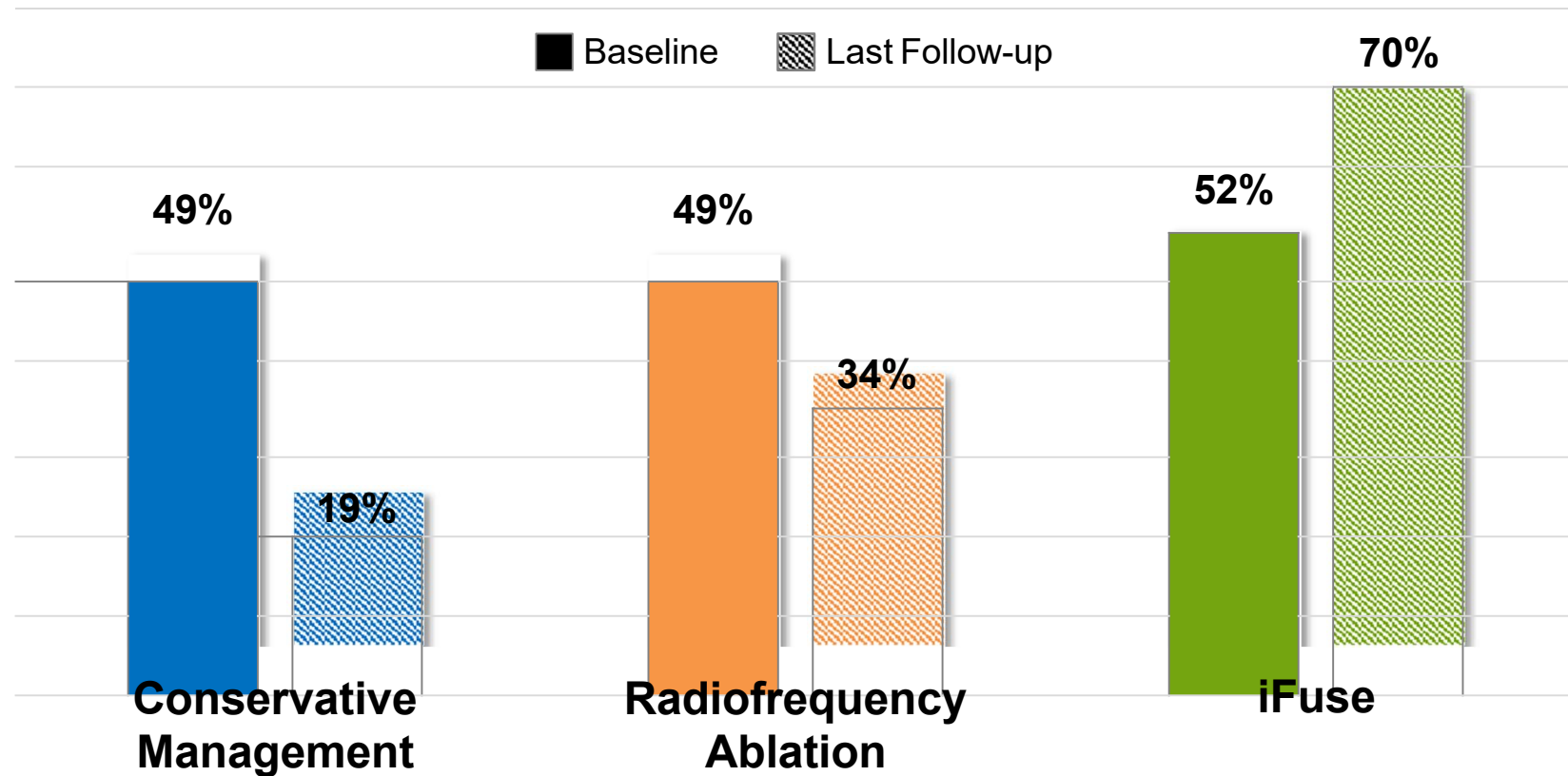
Vanaclocha – Neurosurgery 2017

SI-BONE®

Back to Work

6-year Comparative Study (CM, RF, SI Joint Fusion (iFuse))

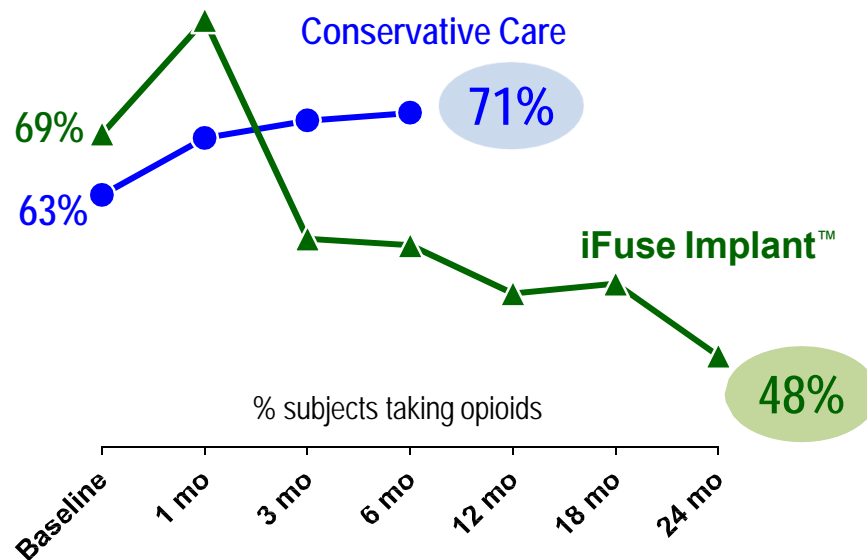
Patients Back Working



iFuse Patients Reduced Opioid Use

2-year RCT

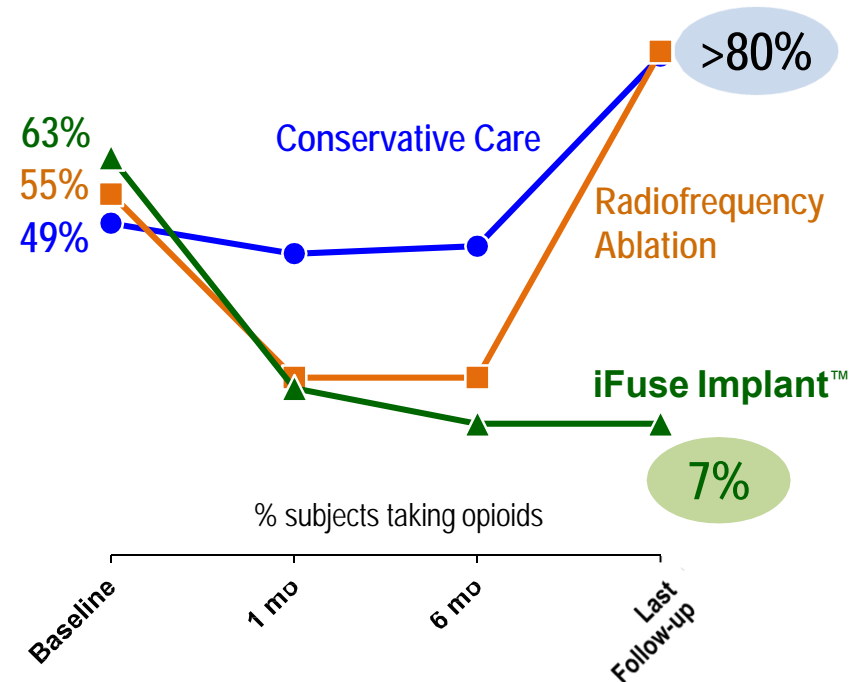
30% completely stopped opioid use



Polly – Int J Spine Surg 2016

6-year Follow-up, 2 controls

ONLY 7% long-term still on opioids

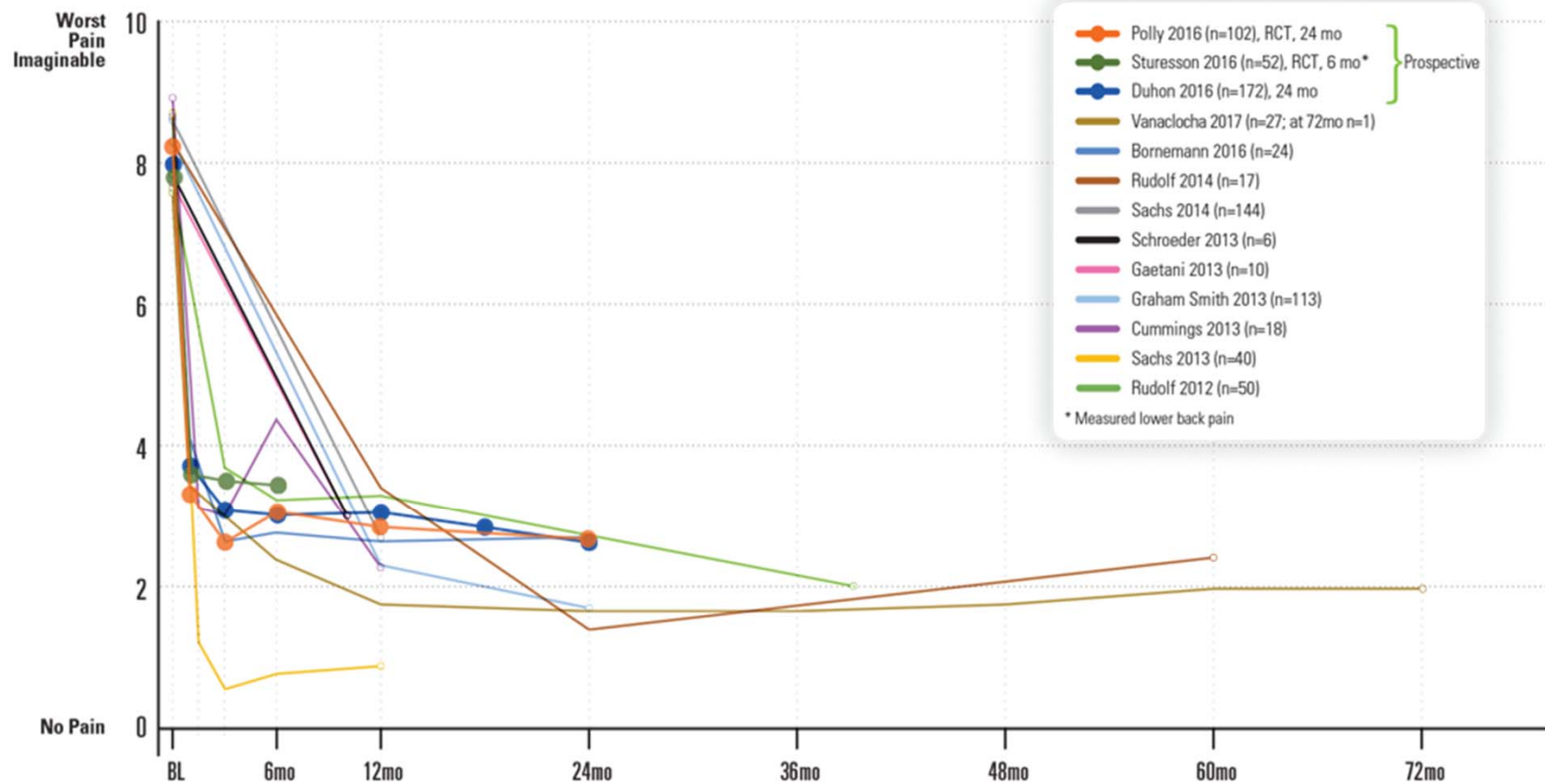


Vanaclocha – Neurosurgery 2017

SI-BONE®

SI Joint Pain

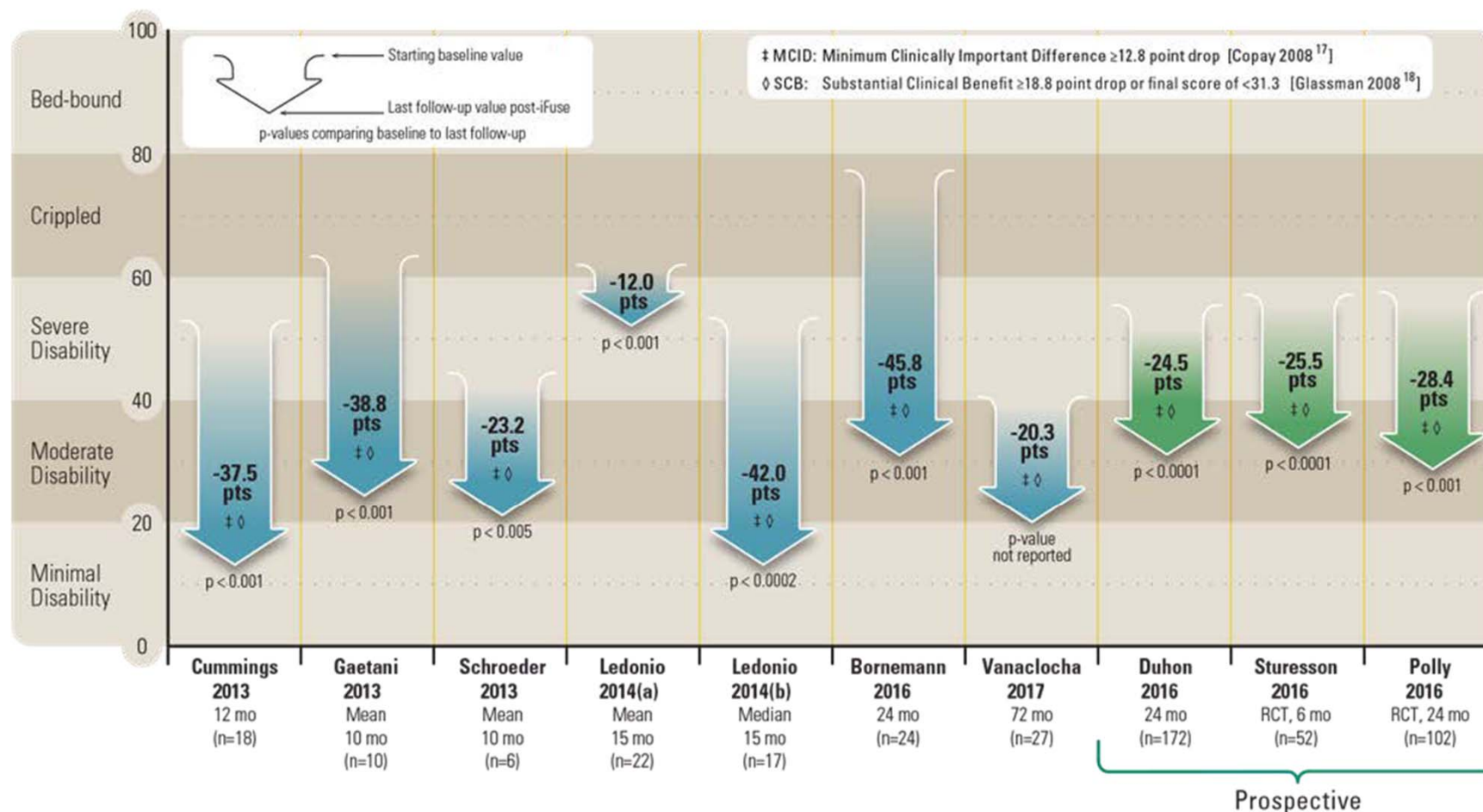
Rapid and Sustained Pain Relief – VAS SI Joint Pain



Complete References in Bibliography

Disability

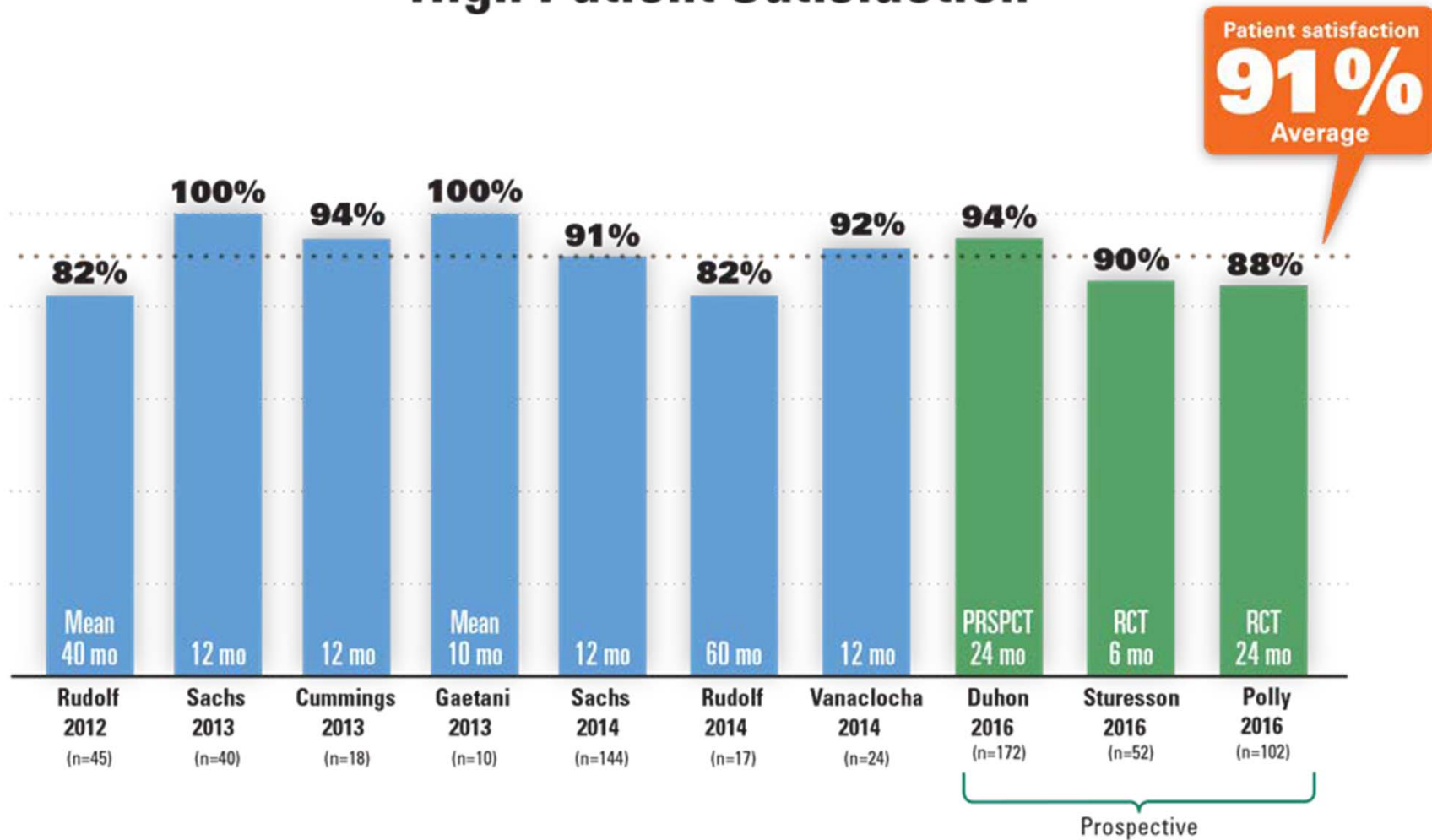
Reduction in Disability – Oswestry Disability Index



Complete References in Bibliography

Satisfaction

High Patient Satisfaction



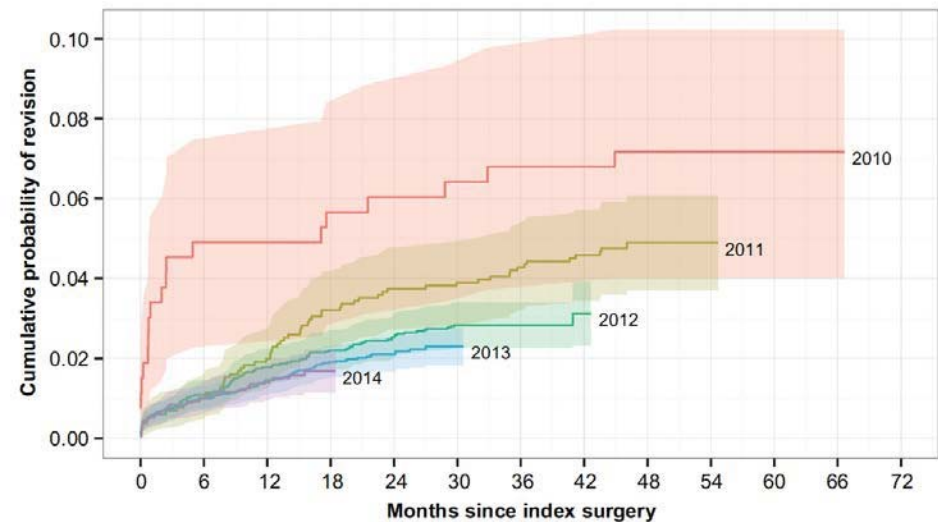
Complete References in Bibliography

Revision Rate

4-yr Revision Rate Study¹

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



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

4-year Cumulative Revision Rate Comparison

3.5%	iFuse, MIS SIJ Fusion (Cher – <i>MDER</i> 2015) ¹
10-12%	Lumbar Decompression (Deyo – <i>JBJS Am</i> 2011)
12-14%	Lumbar Fusion (Martin – <i>Spine</i> 2007)

2.6%

* iFuse Implant System
Overall Revision Rate
(August 2017)

SI-BONE corporate records

1. Cher – *Med Device Evid Res* 2015

Nationwide Medicare Coverage of MIS SIJ Fusion

8 Medicare Administrative Contractors (MACs)



Commercial Coverage

(Status as of August 2017)

iFuse Exclusive Policies



Geisinger
Health Plan

HCSC
Health Care Service Corporation



Professional Society Guidelines

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)

<https://si-bone.com/uploads/documents/PercutaneousSacroiliacJointFusion.pdf>

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)

<http://www.isass.org/public-policy/isass-policy-statement-minimally-invasive-sacroiliac-joint-fusion-july-2016/>

Medical Necessity Documentation 1 of 2

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

Medical Necessity Documentation 2 of 2

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

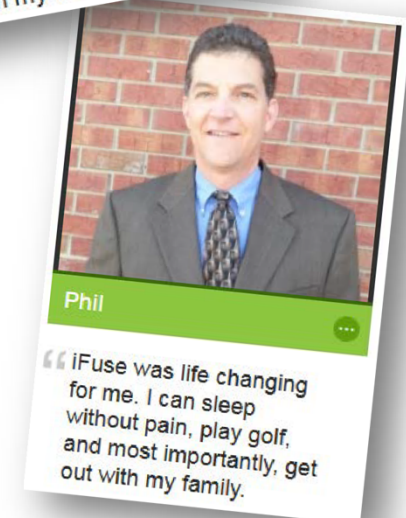
www.sijpc.org

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



Call toll free (844) 742-8339 (844-SI-BUDDY)

Patient Stories



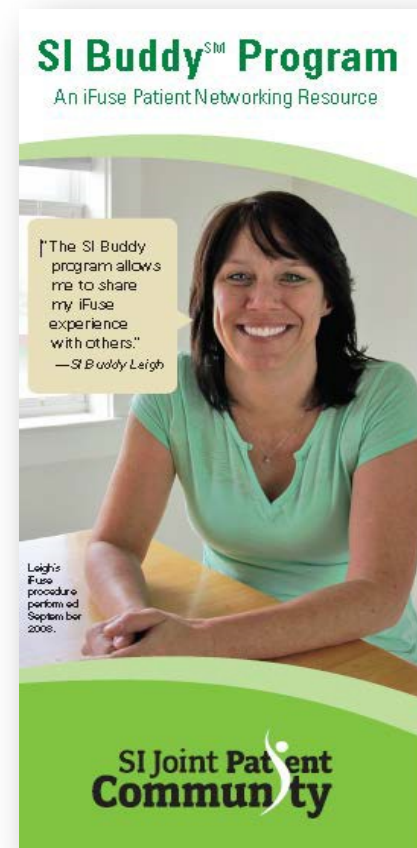
SI-BONE®

SI Joint Patient Community and the SI BuddySM Program

If you are interested in connecting your patients who are considering the iFuse ProcedureTM 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.

Important Information

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.

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Thank You

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