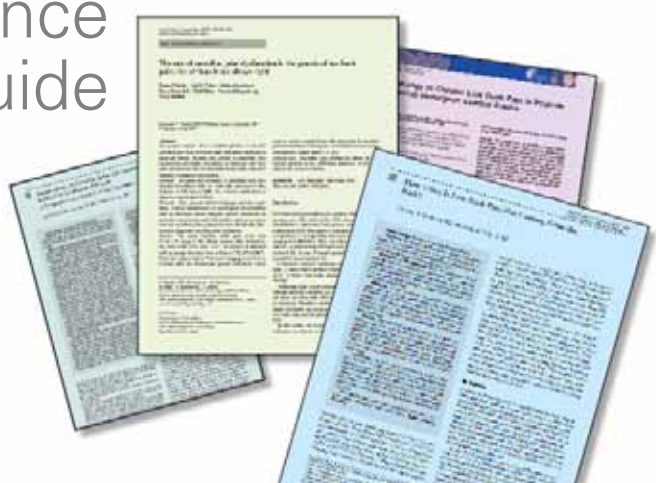
SI-BONE® | **iFuse** Implant System®

Minimally Invasive Sacroiliac Joint Surgery

Clinical Reference Guide



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Prevalence

Bernard, 1987

Recognizing Specific Characteristics of Nonspecific Low Back Pain
Thomas N. Bernard Jr., M.D. and William H. Kirkaldy-Willis, M.D.
Clinical Orthopaedics and Related Research 1987; No. 217: 266-280

- 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.

Cohen, 2005

Sacroiliac Joint Pain: A Comprehensive Review of Anatomy, Diagnosis, and Treatment
Steven P. Cohen, M.D.
Anesthesia and Analgesia 101, no. 5 (November 2005): 1440-1453.

- 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.

Weksler, 2007

The Role of Sacroiliac Joint Dysfunction in The Genesis of Low Back Pain: The Obvious is Not Always Right

Nathan Weksler, M.D. et al.

Archives of Orthopaedic and Trauma Surgery 2007; 127, No. 10: 885-888

- 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%**.

Sembrano, 2009

How Often is Low Back Pain Not Coming from the Back?
Jonathan N. Sembrano, M.D.; David W. Polly Jr., M.D.
Spine 34, no. 1 (January 1, 2009): E27-32

- Consecutive case series evaluation of 200 LBP patients in a single spine surgery practice.
- For patients presenting to a spine surgeon's clinic for LBP, up to **25%** of patients may have significant pain contribution from the hip or SI joints.
- Study found that the 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.

Post-Lumbar Fusion

Maigne, 2005

Sacroiliac Joint Pain after Lumbar Fusion: A Study with Anesthetic Blocks
J. Y. Maigne, M.D. and C.A. Planchon, M.D
European Spine Journal 2005; 14, No. 7: 654-658

- 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.

Ha, 2008

Degeneration of Sacroiliac Joint after Instrumented Lumbar or Lumbosacral Fusion: A Prospective Cohort Study over Five-Year Follow-Up

Ha, et al.,

Spine 33, no. 11 (May 15, 2008): 1192-1198

- Prospective CT imaging assessment of the SI Joint was used to demonstrate degeneration of the SI joint in post-lumbar fusion patients.
- The incidence of SI joint degeneration in patients was **75%** at 5 years post-fusion, which was significantly higher than in the non-fusion group, **38.2%**.
- Among patients with one-segment fusion, **91%** developed SI joint degeneration. Among patients with two-segment fusion, **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.

Ivanov, 2009

Lumbar Fusion Leads to Increases in Angular Motion and Stress Across Sacroiliac Joint

Alexander A. Ivanov, M.D. et al.
Spine 2009; 34, No. 5: E162-169

- 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.

Liliang, 2011

Sacroiliac Joint Pain after Lumbar and Lumbosacral Fusion: Findings Using Dual Sacroiliac Joint Blocks

Po-Chou Liliang, M.D. et al.

Pain Medicine 2011; 12, No. 4: 565-570

- **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.

DePalma, 2011

Etiology of Chronic Low Back Pain in Patients Having Undergone Lumbar Fusion

Michael J. DePalma, M.D. et al.
Pain Medicine 2011; 12: 224–233

- **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.

Diagnosis

Dreyfuss, 2004

Sacroiliac Joint Pain
Paul Dreyfuss, et al.,
The Journal of the American Academy of Orthopaedic Surgeons 12, no. 4 (August 2004): 255-265.

- The SI joint is a source of pain in lower back and buttocks in approximately **15%** of the population.
- In one study with the SI joint established as the primary pain source: 94% of patients had pain in the buttocks, 48% in the thigh, 28% the lower leg, 13% foot/ankle, 14% groin, and 2% abdomen.
- **Differential Diagnosis** - SI joint pain can be confirmed by controlled, fluoroscopy guided or CT-guided, contrast-enhanced anesthetic injection procedures.

Laslett, 2005

Diagnosis of Sacroiliac Joint Pain: Validity of Individual Provocation Tests and Composites of Tests

Mark Laslett, Ph.D. et al.

Manual Therapy 10, no. 3 (August 2005): 207-218

- This study examined the diagnostic power of pain provocation SIJ tests singly and in various combinations, in relation to an accepted criterion standard.
- Three or more out of six tests or any two of four selected tests have the best predictive power in relation to results of intra-articular anaesthetic block injections.

Szadek, 2009

Sacroiliac Joint Pain

Szadek, et al.
Diagnostic Validity of Criteria for Sacroiliac Joint Pain.
Journal of Pain, 2009: 10(4) 354-368

- Review of clinical studies focused on the diagnostic validity of the IASP criteria for diagnosing SI joint pain as proposed by the International Association for the Study of Pain (IASP).
- The thigh thrust test, compression test, and three or more positive stressing tests showed discriminative power for diagnosing SI joint pain.
  - 3 of 5 must be positive (Thigh Thrust, Compression, Gaenslen, FABER, Distraction)
  - 1 of 3 positive results must be Thigh Thrust or Compression
- In all studies, the SI joint selective infiltration was used as a gold standard.
- This article is the basis of SI-BONE's diagnostic algorithm.

Sembrano, 2011

Diagnosis and Treatment of Sacroiliac Joint Pain
Jonathan N. Sembrano M.D., Mark A. Reiley M.D., David W. Polly Jr., M.D. and Steven R. Garfin, M.D.
Current Orthopaedic Practice 22, no. 4 (2011): 344-350.

- Since many treatment modalities, and especially surgical treatment, are disease-specific or site-specific, it is likely that a significant cause of failed low back pain treatment is failure to identify the correct pain generator.
- The SI joint is a significant component of low back pain (LBP), and most spine care providers are 'reluctant or unaware' of SI joint as a cause of LBP.
- **Differential diagnosis** of LBP including the SI joint is important to get to effective treatment.

Treatment Options / Results

Buchowski, 2005

Functional and Radiographic Outcome of Sacroiliac Arthrodesis For The Disorders of The Sacroiliac Joint

Jacob M. Buchowski et al.

The Spine Journal: Official Journal of the North American Spine Society 5, no. 5 (October 2005): 520-528; discussion 529

- 20 patients undergoing sacroiliac joint arthrodesis (via a modified Smith-Petersen technique) between Dec. 1994 and Dec. 2001.
- Significant ($p \leq .05$) 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.

Zelle, 2005

Sacroiliac Joint Dysfunction: Evaluation and Management
Boris A. Zelle, M.D. et al.
The Clinical Journal of Pain 21, no. 5 (October 2005): 446-455

- 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 anaesthetic 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.

Cohen, 2009

Outcome Predictors for Sacroiliac Joint (Lateral Branch) Radiofrequency Denervation

Steven P. Cohen, M.D. et al.
Regional Anesthesia and Pain Medicine, Volume 34, Number 3, (May-June 2009): 206-214

- The purpose of this study was to determine whether any demographic or clinical variables can be used to predict SI joint RF denervation outcome.

- Findings demonstrate no significant association between the degree of pain relief after a single local anesthetic medial branch block and lumbar facet RF outcomes and the uniformly high success rates reported in previous SI joint denervation studies, regardless of the use of multiple prognostic blocks.

ISASS Presentation, 2011

Retrospective Evaluation of Minimally Invasive Surgical (MIS) Method for Sacroiliac Joint Arthrodesis

Presented by Frank Phillips, M.D.

International Society for the Advancement of Spine Surgery
11th Annual Meeting, April 26 - April 29, 2011 Las Vegas, NV

- Clinically significant results at 3, 6, and 12 months post-op vs. pre-op
- 90% of responding patients indicated at 12 moths that they would have the procedure again
- The sacroiliac (SI) joint is a common symptom generator in patients with low back problems

Glaser, 2011

Radiographic and Surgical Outcome of Percutaneous Sacroiliac Joint Fixation with Porous Plasma-Coated Triangular Titanium Implants: An Independent Review
Presented by John A. Glaser, M.D.
The Clinical Orthopedic Society Annual Meeting 2010 Charleston, SC

- Independent radiographic and surgical assessments of 31 consecutive patients who underwent the iFuse procedure.
- On 6 month post-op CT scan, 18/19 patients had radiographic evidence of bone ingrowth, and bone into or across the SI joint was evident in 8/19 patients.
- When patients with chronic disabling SI joint pain fail conservative treatments, minimally invasive surgery (MIS) SI fixation and arthrodesis is an option for carefully selected group of patients.

Sheep Study, 2011

Achieving Minimally Invasive Sacroiliac Joint (SIJ) Fusion Without Bone Graft – Preliminary Results from an Ovine Model of SIJ Fusion

Paul A. Anderson, M.D., et al.,
SI-BONE White Paper 2011

- Nine skeletally mature, female sheep were implanted with two 4.0 x 40 mm iFuse implants placed across the left SIJ.
- The post-operative bone mineral density was significantly greater than the pre-operative density in all regions around the implant.
- Bony bridging across the SIJ occurred in 6/9 (67%) specimens at 12 weeks and 8/9 (89%) specimens at 24 weeks.
- There was no device migration identified at any time point.

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